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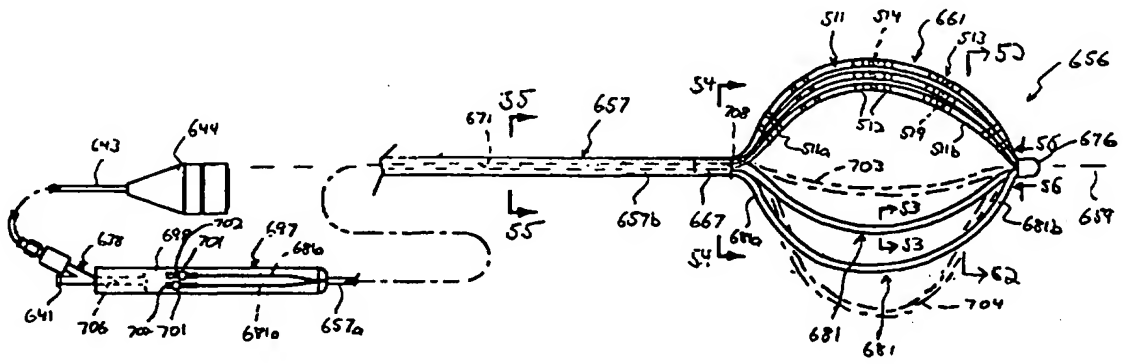

(57) Abstract

A catheter probe (501) is provided for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber. The catheter probe includes a flexible elongate tubular member (502) having proximal and distal extremities (502a, 502b) and a lumen (576) extending therebetween. A plurality of longitudinally-extending spaced-apart arms (511) having interconnected proximal and distal extremities (511a, 511b) are carried by the distal extremity of the flexible elongate tubular member. The arms are movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis of the catheter probe. The arms subtend an angle of approximately 180° or less about the longitudinal axis when in the expanded position. A plurality of longitudinally spaced-apart electrodes (512) are carried by each of the arms. Electrical conductors (541) extend through the elongate tubular member and are connected to the electrodes for performing electrical functions with respect to the electrodes. A wire (611) is slidably carried within the lumen for causing the arms to move to the expanded position. The electrodes carried by the arms can be urged against a portion of the wall of the heart when the arms are in the expanded position to map the portion of the wall.

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ENDOCARDIAL MAPPING AND/OR ABLATION CATHETER PROBE AND METHOD

This is a continuation-in-part of Application Serial No. 08/555,927 filed November 13, 1995, which is a continuation-in-part of Application Serial No. 08/326,666 filed October 19, 1994.

This invention relates to an endocardial mapping and/or ablation catheter probe and method of treatment.

Endocardial mapping and ablation catheters with mapping and/or ablation basket assemblies carried by their distal extremities have heretofore been provided. The construction of these basket assemblies sometimes leads to the formation of thrombus thereon. There is therefore a need for a new and improved endocardial mapping and ablation system for inhibiting the formation of thrombus thereon.

In general it is an object of the present invention to provide an endocardial mapping and ablation system which has webbing between the interconnected arms of the basket-like mapping assembly for inhibiting the formation of thrombus thereon.

Another object of the invention is to provide a system of the above character having an atraumatic tip for inhibiting the creation of trauma when the basket-like assembly is urged against the apex of a chamber in the heart.

Another object of the invention is to provide a system of the above character in which the arms of the basket assembly are asymmetrically spaced apart in a group for permitting high density mapping of a portion of the heart wall.

Another object of the invention is to provide a system of the above character in which a plurality of electrodes are clustered in a group on the arms of the basket-like assembly.

Another object of the invention is to provide a system of the above character in which additional basket arms are provided along the opposite side of the basket-like assembly from the electrode-carrying arms for urging the electrodes against the heart wall.

Another object of the invention is to provide a system in which the additional basket arms are slidably carried by the catheter shaft so as to be adjustably bowed outwardly against the heart wall.

Another object of the invention is to provide a system of the above character in which a pull wire is connected to the interconnected distal extremities of the arms of the basket-like assembly for selectively adjusting the shape of the basket-like assembly.

Another object of the invention is to provide a system of the above character in which the pull wire is pushable so as to aid in the contraction of the basket-like assembly.

Another object of the invention is to provide a method for mapping the apex of a chamber of the heart.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

FIG. 1 is a schematic illustration of an endocardial mapping and ablation system end catheter probe incorporating the present invention.

FIG. 2 is an enlarged plan view showing in particular the flexible sheet used to form the cylindrical member at the distal extremity of the catheter probe shown in FIG. 1.

FIG. 3 is an enlarged detail view of a portion of one of the arms of the cylindrical member showing the spring metal strip used in the arm.

FIG. 4 is an enlarged cross sectional view taken along the line 4-4 of FIG. 2.

FIG. 5 is an enlarged cross-sectional view taken along the line 5-5 of FIG. 2.

FIG. 6 is an enlarged detail view partially in cross section of the distal extremity of the catheter probe.

FIG. 7 is a cross-sectional view taken along the line 7-7 of FIG. 2.

FIG. 8 is an enlarged cross-sectional view taken along the line 8-8 of FIG. 2.

FIG. 9 is a cross-sectional view taken along the line 9-9 of FIG. 2.

FIG. 10 is a schematic diagram of the electronic circuitry utilized in the system for performing the method of the present invention.

FIG. 11 is a cross-sectional view of the heart showing the manner in which the system and catheter probe of the present invention are employed in the right ventricle to achieve mapping and/or ablation in accordance with the method of the present invention.

FIG. 12 is a cross-sectional view taken along the line 12-12 of FIG. 11.

FIG. 13 is a timing diagram for the circuitry shown in FIG. 10.

FIG. 14 is a partial view of another sheet incorporating the present invention for use with a catheter probe which shows a plurality of chips carried thereby.

FIG. 15 is a cross sectional view of a catheter probe showing the manner in which the plurality of chips shown in FIG. 14 are radially disposed about a mandrel for the catheter probe.

FIG. 16 is a partial plan view of another catheter probe incorporating the present invention and for use with the system and method of the present invention.

FIG. 17 is a cross sectional view taken along the line 17-17 of FIG. 16.

FIG. 18 is a cross sectional view taken along the line 18-18 of FIG. 17.

FIG. 19 is a partial elevational view showing the catheter probe of FIG. 16 with the expandable means in an expanded position.

FIG. 20 is a cross-sectional view taken along the line 20-20 of FIG. 19.

FIG. 21 is a plan view of an alternative bipolar electrode for use with the present invention.

FIG. 22 is a side elevational view of another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 23 is a cross-sectional view of the catheter probe of FIG. 22 taken along the line 23-23 of FIG. 22.

FIG. 24 is an enlarged side elevational view, partially sectioned, of the catheter probe of FIG. 22 taken along the line 24-24 of FIG. 22.

FIG. 25 is a cross-sectional view of the catheter probe of FIG. 22 taken along the line 25-25 of FIG. 22.

FIG. 26 is a cross-sectional view of the catheter probe of FIG. 22 taken along the line 26-26 of FIG. 22.

FIG. 27 is a cross-sectional view of the catheter probe of FIG. 22 taken along the line 27-27 of FIG. 26.

FIG. 28 is a cross-sectional view, partially cut away, of the catheter probe of FIG. 22 taken along the line 28-28 of FIG. 27.

FIG. 29 is a cross-sectional view of the heart showing the manner in which another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention is employed in the right ventricle.

FIG. 30 is side elevational view of the distal extremity of the catheter probe of FIG. 29.

FIG. 31 is a cross-sectional view of the catheter probe of FIG. 29 taken along the line 31-31 of FIG. 30.

FIG. 32 is a cross-sectional view of the catheter probe of FIG. 29 taken along the line 32-32 of FIG. 31.

FIG. 33 is side elevational view, similar to FIG. 30, of the distal extremity of another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 34 is side elevational view, similar to FIG. 30, of the distal extremity of a further embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 35 is side elevational view, similar to FIG. 30, of the distal extremity of yet another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 36 is a cross-sectional view of the heart showing the manner in which still another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention is employed in the right ventricle.

FIG. 37 is side elevational view of the distal extremity of the catheter probe of FIG. 36.

FIG. 38 is a cross-sectional view of the catheter probe of FIG. 36 taken along the line 38-38 of FIG. 37.

FIG. 39 is a side elevational view of another embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 40 is cross-sectional view of the catheter probe of FIG. 39 taken along the line 40-40 of FIG. 39.

FIG. 41 is a top plan view, partially cut away, of the catheter probe of FIG. 39 taken along the line 41-41 of FIG. 39.

FIG. 42 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 42-42 of FIG. 41.

FIG. 43 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 43-43 of FIG. 41.

FIG. 44 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 44-44 of FIG. 41.

FIG. 45 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 45-45 of FIG. 41.

FIG. 46 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 46-46 of FIG. 41.

FIG. 47 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 47-47 of FIG. 41.

FIG. 48 is a cross-sectional view of the catheter probe of FIG. 39 taken along the line 48-48 of FIG. 40.

FIG. 49 is a cross-sectional view, partially cut away, of the catheter probe of FIG. 39 taken along the line 49-49 of FIG. 48.

FIG. 50 is a cross-sectional view, partially cut-away, of the catheter probe of FIG. 39 taken along the line 50-50 of FIG. 39.

FIG. 51 is a side elevational view of a further embodiment of the endocardial mapping and/or ablation catheter probe of the present invention.

FIG. 52 is cross-sectional view of the catheter probe of FIG. 51 taken along the line 52-52 of FIG. 51.

FIG. 53 is a cross-sectional view of the catheter probe of FIG. 51 taken along the line 53-53 of FIG. 51.

FIG. 54 is a cross-sectional view of the catheter probe of FIG. 51 taken along the line 54-54 of FIG. 51.

FIG. 55 is a cross-sectional view of the catheter probe of FIG. 51 taken along the line 55-55 of FIG. 51.

FIG. 56 is a cross-sectional view, partially cut away, of the catheter probe of FIG. 51 taken along the line 56-56 of FIG. 51.

FIG. 57 is a side elevational view of the catheter probe of FIG. 22 taken along the line 57-57 of FIG. 22.

In general, a catheter probe is provided for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber. The catheter probe includes a flexible elongate tubular member having proximal and distal extremities. A lumen extends along a longitudinal axis between the proximal and distal extremities. A plurality of longitudinally-extending spaced-apart arms having interconnected proximal and distal extremities are carried by the distal extremity of the flexible elongate tubular member. The arms are movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis. The arms subtend an angle of approximately 180° or less about the longitudinal axis when in the expanded position. A plurality of longitudinally spaced-apart electrodes are carried by each of the arms. Electrical means extends through the elongate tubular member and is connected to the electrodes for performing electrical functions with respect to the electrodes. A wire is slidably carried within the lumen and has proximal and distal end portions. The distal end portion of the wire is secured to the distal extremities of the arms. Means is carried by the proximal extremity of the flexible elongate tubular member for pulling the proximal end portion of the wire to cause the arms to move to the expanded position. The electrodes carried by the arms can be urged against a portion of the wall of the heart when the arms are in the expanded position to map said portion of the wall.

More in particular, the endocardial mapping and ablation system 21 as shown in the drawings consists of a catheter probe 22 which is provided with a high voltage connector 23 and a signal connector 24 that are connected to mating connectors 26 and 27 forming a part of a cable 28. Cable 28 is connected to a catheter interface module 29 which supplies and receives appropriate signals to and from a computer 31 that is provided with a disc drive 32 and a monitor 33. It is also provided with a keyboard (not shown) for use in controlling the operation of the computer.

The catheter probe 22 consists of a flexible elongate tubular member 36 formed of a suitable material such as plastic which is circular in cross section as shown in FIG. 7. The tubular member 36 has a suitable diameter as for example 0.10" to .150" and a suitable length as for example from 100 to 150 cm. The tubular member 36 is provided with proximal and distal extremities 37 and 38 and is provided with at least one lumen and as shown in FIG. 9 is provided with three lumens 39, 41 and 42 in which lumen 39 is a centrally disposed lumen and lumens 41 and 42 are two generally crescent-shaped lumens provided on opposite sides of the lumen 39. Both lumens 39 and 41 extend from the proximal extremity 37 to the distal extremity 38 of the tubular member 36.

A flexible expandable cylindrical member 46 is secured in a fixed position to the distal extremity of the flexible elongate tubular member 36. The expandable cylindrical member 46 is movable between contracted and expanded positions as hereinafter described. The expandable cylindrical member is provided with a plurality of circumferentially spaced apart longitudinally extending flexible arms 47 having adjoined proximal and distal extremities or end portions 48 and 49 (see FIG. 6).

The flexible expendable cylindrical member is formed from a flexible flat sheet 51 (see FIG. 2) which is in the form of an elongate rectangle having sideways extending ears 52 and 53 on opposite ends. The sheet 51 is formed of a suitable insulating material such as plastic. One plastic found particularly suitable is a polyamide identified as Kapton (trademark). Assuming that the plurality of arms 47 to be utilized in the cylindrical member 46 is eight, the sheet 51 is slitted with a knife or die (not shown) to provide parallel spaced apart slits 56 extending longitudinally between the ears 52 and 53 to form the plurality of circumferentially spaced longitudinally extending arms 47. Small holes 57 are provided on the opposite ends of each of the slits 56 and serve to prevent propagation of the 56 slits into the proximal and distal extremities or end portions 48 and 49 of the sheet 51.

In order to impart springiness to the arms, the sheet 51 can be formed of two plastic sheets bonded together over die cut metal strips 61 of a suitable material such as stainless steel or plastic having narrowed portions 61a (see FIG. 3) so that the metal strips 61 are embedded between the two layers 62 and 63 of plastic (see FIG. 4) and encapsulated therein so that they lie in the areas between the lines in which the slits 56 are to be cut. In certain applications of the present invention, it may be desirable to form the strips 61 with a particular pattern to achieve a desired conformation for the bowing out of arms 47 of the expandable cylindrical member 46 when it is expanded as hereinafter

described. The narrowed portion 61a can be provided at the proximal extremity to achieve greater bonging of the arm 47 in that region as the cylindrical member 46 is expanded as hereinafter described. The stainless steel strips can have a desired width, as for example, less than the width of the arms 47 and can have a suitable thickness as for example 0.001" to 0.010" in thickness and the plastic layers 62 and 63 can have a suitable thickness ranging from 0.001" to 0.010" in thickness and typically a thickness of .002".

Radially spaced apart rectangular radiopaque markers 64 formed of a suitable material such as lead or platinum can be positioned so that they underlie the stainless steel strips 61 and are embedded between the layers 62 and 63 of the layers 62, 63 and 64 forming the sheet 51. As shown in FIG. 2, the markers 65 are staggered in distance from the distal extremity so that they form a portion of a helix when the sheet 51 is formed into the cylindrical member 46 as hereinafter described. The markers 65 are only placed on certain of the arms 47 as for example five of the eight arms shown in FIG. 2. This aids in ascertaining the rotational position of the member 46 under fluoroscopy as hereinafter described.

A plurality of longitudinally end radially spaced apart sets 66 of bipolar electrodes 67 and 68 are provided on the exterior surfaces 69 of the arms 47 which serve as insulating substrates and are spaced laterally of sheet 51 (see FIG. 6) and circumferentially around the cylindrical member 46 (see FIG. 6). The cylindrical member 46 serves as an expandable means secured to the distal extremity of the tubular elongate element 36 and is movable between contracted and expanded positions whereby when the expandable means is moved to the expanded position the electrodes 67 and 68 are brought into engagement with the wall of the heart forming the chamber in which the expandable means is disposed as hereinafter described.

The electrodes 67 and 68 as shown are rectangular in shape and can have a length of 0.040" and a width of 0.040". The bipolar electrodes 67 and 68 can be separated by a suitable distance as for example 0.040". If desired the electrodes 67 and 68 can be of different sizes. Leads 71 are provided on the interior or inner surfaces 72 of the arms 47. The electrodes 67 and 68 and the leads 71 are formed of a suitable conductive materials. The outer or exterior surfaces 69 and the inner or interior surfaces 72 of the arm 47 of sheet or substrate 51 are coated with vapor deposited or electroplated layer of a suitable conductive metal such as copper to provide a copper layer 73 of a suitable thickness as for example 0.0005". The sheet 51 is then drilled to form holes 74 extending between the copper layers 73. Additional conductive material such as copper is then plated through the holes 74 to form the vies 76 (see FIG. 5). Thereafter, conventional etching techniques are used to remove the undesired copper material on the outer surfaces 69 and on the inner surfaces 72 of the arms 47 so that there remains longitudinally spaced apart electrodes 67 and 68 on the outer surface 69 and laterally spaced apart longitudinally extending leads 71 which are connected to the sets 66 of electrodes 67 and 68 by the vies 76. Each of the electrodes 67 and 68 is connected to one of the leads 71 by a via 76. The leads 71 are insulated from the metal strips 61 by the plastic layer 63.

The electrodes 67 and 68 as well as the leads 71 can be augmented by plating onto the copper layer 73. Thus, as shown in FIG. 5, the electrode 67 can be augmented by depositing a nickel layer 77 on the copper layer 73 followed by a gold layer 78 deposited on the nickel layer 77. Gold is particularly suitable as a final layer in this application because it is inactive in blood. It also is an excellent conductor.

The proximal end of the sheet 51 shown in FIG. 2 is provided with an extension 81. A multiplexer chip 86 of the type hereinafter described is mounted on or attached to extension 81 by conventional bonding techniques and is connected by conventional techniques to the leads 74 connected to the electrodes 67 and 68. In forming the sheet 51 of FIG. 2 into the cylindrical member 46, a distal mandrel 91 and a proximal mandrel 92 are utilized. The distal mandrel 91 is cylindrical in form and can be formed of a suitable material such as plastic or metal. The distal mandrel 91 is provided with a centrally disposed hole 93 which is provided with an outwardly flared portion 93a. The proximal mandrel 92 is also formed of a suitable material such as plastic and is provided with a cup-like recess 96 (see FIG. 6). It is also provided with a hole 97 which curves slightly downwardly to clear the recess 96 and extends through the mandrel 92. An additional hole 98 is provided in the mandrel 92 which opens into recess 96.

The sheet 51 is wrapped into a cylinder with the ears 52 overlapping the ears 53 by inserting the ears 52 through T-shaped slots 99 formed in the ears 53 and having pairs of spaced-apart slits 101 mating with the slots 99 so that the outer side margins

of the sheet 51 are brought together to form another slit 56 between the two adjacent arms 47. The ears 52 and 53 also can be overlapped and fastened together on themselves by suitable means such as an adhesive. When fabricated in this manner, the cylindrical member 46 typically would have a diameter of approximately 0.150" and a suitable length as for example 2 1/2" depending upon the size of the cavity in the heart to be mapped.

During wrapping of the ears 52 and 53 around the mandrel 91, the extension 81 and the chip 86 thereon is positioned within the cup-shaped recess 96. An encased crystal 102 is also mounted in the recess 96 overlying the chip 86. An RC oscillator (not shown) on the chip 86, may be used in place of crystal 102. The recess 96 is enclosed by semi-cylindrical cover 103. Prior to the placement of the cover 103, the chip 86 and the crystal 102 may be encapsulated in a suitable epoxy 104 placed in recess 96. The epoxy 104 can have heat sinking capabilities to dissipate any heat generated within the chip 86.

An alternative embodiment for the mounting of the multiplexer chip 86 is shown in FIGS. 14 and 15. As shown therein, the multiplexer chip 86 instead of being in only a single package as shown in FIGS. 2 and 6 can have its circuitry as well as other circuitry supplied in a plurality of chips, as for example, chips 86a, 86b and 86c which are mounted on the sheet 51 on the proximal end portion 49 immediately adjoining the ears 52 and the proximal extremities of the arms 47 so that the leads carried by the arms and connected to the electrodes 67 and 68 can be connected directly to the chips 86a, 86b and 86c. Chips 86a, 86b and 86c are spaced apart a suitable distance so that when the sheet 51 is wrapped about the proximal mandrel 92a shown in FIG. 15, the chips 86a, 86b and 86c are received within circumferentially spaced-apart recesses 96a, 96b and 96c provided in the proximal mandrel 92a. Such an arrangement has an advantage in that it makes it possible to provide additional circuitry if desired in the flexible elongate member 36 in close proximity to the electrodes 67 and 68. Also it permits the hole 97a (see FIG. 15) to be centrally disposed in the proximal mandrel 92a so that the pull wire 116 (hereinafter described) extending therethrough can extend along the center axis of the mandrel 92 rather than being offset as shown in FIG. 6.

A band 106 formed of a suitable conducting metal such as gold is provided at the distal extremity of the cylindrical member 46 over the mandrel 91 and serves as a ground. Alternatively, a large surface area electrode may be placed on the chest of the patient (not shown) to serve as a ground for the ablation current. A tubular sleeve 105 is fitted over the proximal mandrel 92 and extends over the proximal extremity of the cylindrical member 46. The sleeve 103 can be formed of a suitable material such as injection molded plastic. It can be formed as a separate sleeve or can be formed integral with the flexible elongate tubular member 36 forming the probe catheter 22 to provide a one-piece construction.

With respect to the embodiment shown in FIGS. 1-9, the tubular member 36 is rotationally aligned so that its central lumen 39 is in alignment with the hole 98 in the proximal mandrel 92. Because of the multiplexing capabilities of the chip 86 a relatively small number of wires or conductors 108 are connected to the chip 86. For example, as few as seven insulated conductors 108 can be provided which are bonded to pads (not shown) connected to the chip 86. The conductors 108 extend through the hole 98 and into the crescent-shaped lumens 41 and 47 provided in the flexible elongate member 36. The conductors 108 extend through the flexible elongate cylindrical member 36 and are connected to the connectors 23 and 24 heretofore described.

Seven conductors 108 would be provided when bipolar mapping and ablation is desired. Rather than using a single connector for all of the wires or conductors 108, it is desirable to separate the conductors into a high voltage set of conductors and a signal set of conductors. Thus, with seven conductors, the four conductors associated with high voltage can be connected into the quadrapole connector 23 and the three wires of the signal set can be connected into a biaxial connector 24.

Another tubular member 111 is connected to the proximal extremity 37 of the tubular member 36 and is provided with a lumen 112 which is in registration with the central lumen 39 provided in the tubular member 36. An elongate pull wire 116 is disposed in the lumens 112 and 39 and is formed of a suitable material such as stainless steel and can have a size as for example .014" in diameter. The pull wire 116 extends the length of the tubular member 36 and extends into the lumen 97 provided in the proximal mandrel 92 and then into the interior of the flexible expandable cylindrical member 46 which also may be called a cylindrical expandable electrode array and through the hole 93 provided in the distal mandrel 91. After the pull wire or element 116 has been inserted into the catheter and through the hole 93 of the mandrel 91, the distal extremity of the pull wire or element

116 is provided with an enlarged portion 116a which can be formed integral with the pull wire or element 116 or can be formed as a separate part bonded to the distal extremity of the pull wire. The portion 116a has a size which is sufficiently great so that it cannot be pulled through the hole 93 but which is still small enough to seat within the flared portion 93a of the hole 93 and not protrude substantially beyond the distal extremity of the mandrel 91. The pull wire 116 is provided with a knob 117 on its proximal extremity for operation of the pull wire.

Operation and use of the catheter or probe 22 in connection with the catheter interface module 29 and the computer 31 of the system 21 may now be briefly described as follows in utilizing the present invention. The catheter probe 22 is first used with the cylindrical expandable member or electrode array 46 in its normal contracted position which can be ensured by pushing on the knob 117 to fully extend the pull wire 116 to extend beyond the mandrel 91 so that it can serve as a guide wire. The catheter or probe 22 is inserted into a cavity 131 of the heart 132 (FIG. 11) as for example the right ventricle of the heart in a human body by access through a femoral vein. This can be accomplished in a conventional manner by introducing the guide wire or pull wire or element 116 and thereafter the distal extremity of the catheter probe 22 into the femoral vein by the use of a guide sheath and/or a guiding catheter. This can be done in a conventional manner under fluoroscopy in which the catheter or probe 22 can be introduced through the superior inferior vena cave into the right atrium and then advanced into the right ventricle as shown particularly in FIGS. 11 and 12. In connection with this procedure, the pull wire 116 can be utilized as a guide wire and can be rotated by rotating the knob 117 to facilitate advancing the catheter through the desired path into the vessel lumen leading to the heart.

As soon as the distal extremity of the catheter probe 22 is positioned within the desired cavity of the heart as for example the right ventricle 131 of a heart 132 as shown in FIG. 11, connectors 23 and 24 can be interconnected with the mating connectors 26 and 27 so that the catheter probe 22 is connected to the catheter interface module 29 and the computer 31. Once this has been accomplished, the pull knob 117 can be retracted to move the portion 116a of the pull wire into the recess 93a and upon further pulling movement to cause expansion of the cylindrical expandable member or electrode array 46 to cause its arms 47 to be bowed outwardly as shown in FIG. 11 with the distal extremity or tip of the cylindrical electrode array 46 touching the distal extremity or apex of the right ventricle 131 so that the arms and the electrodes 67 and 68 carried thereby are brought into contact with the wall of the heart forming the right ventricle. As shown in FIG. 11, the bowing of the arms 47 is more pronounced at the proximal extremity 48 and at the distal extremity 49 of each of the arms 47. This increased bowing is made possible by providing the narrowed portions 61a on the proximal and distal extremities of the metal strips 61 as hereinbefore described. The flexibility of the arms 47 permits the heart to continue its normal beating pattern in moving the wall forming the right ventricle 131 inwardly and outwardly. At the same time because the arms 47 are spread or spaced apart as they are bowed outwardly, there is ample space between the arms so that normal blood flow in the right ventricle 131 can occur substantially unimpeded by the electrode array 46 when the array 46 is in the chamber. The springiness of the arms 47 is such that the arms 47 will yieldably follow the muscular contractions and expansions of the right ventricle and keep the bipolar electrodes 67 and 68 in substantially continuous contact with the heart wall and the electrical circuitry provided in the heart wall.

It should be appreciated that similar procedures can be used for positioning the catheter probe 22 in other chambers of the heart as for example the left ventricle of the heart. In the embodiment shown in FIGS. 1-13, eight arms 47 are provided with six sets of electrode pairs with four of the arms having an additional sets of each end each for a total of 112 electrodes and 56 electrode pairs. Fewer bipolar pairs are provided at the ends because the arms 47 are closer together at the ends when the cylindrical expandable member 46 is expanded. Each bipolar electrode pair is connected to a differential amplifier 141 (see FIG. 10). Each of the differential amplifiers 141 is provided with input circuitry 142 which consists of current limiting resistors R1 and R2 connected to diodes D1 and D2 on opposite sides of the input line with the diode D2 being connected to ground and diode D1 being connected to a positive voltage. Diodes D3 and D4 are connected to the other input line with diode D4 being connected to ground and diode D3 being connected to the positive voltage. These serially connected diodes serve to protect the inputs to the amplifiers 141 during the time that ablation voltages are being applied as hereinafter described. The input circuitry has the

capability of limiting the voltage rise at the inputs of the amplifier 141 to approximately 1/2 volt. The differential amplifiers 141 have a suitable gain as for example typically between 100 and 500. Since the endocardial signals that are received from the heart are of relatively high amplitude, a very high gain is not required from the amplifiers 141.

The outputs of the amplifiers 141 are connected by 56 lines 142 also the multiplexer 146 identified from 1 to 56 to an analog multiplexer 146 the multiplexer 146 can have a suitable number of inputs as for example 64 inputs as shown. Inputs 1-56 are connected to the cylindrical expandable member 46. Inputs 57-58 can be grounded as shown. Inputs 59-62 can be connected to a positive voltage supply and inputs 63-64 are connected to ground. One or two of these inputs can be utilized for providing a synchronization signal for demultiplexing as hereinafter described.

The multiplexer 146 is driven by a 6 bit binary counter 151 which is supplied with a clock frequency from an oscillator 152 that is controlled by crystal 153 of a suitable frequency as for example, 200 KHz. The 200 KHz oscillator frequency provides a five microsecond cycle length per channel as shown in the waveform. The counter 151 supplies an output 156 in FIG. 13, on six lines 157 to the multiplexer 146. The multiplexer 146 is provided with an output 158 which is controlled by the binary counter 151 so that the output from each of the amplifiers 141 appears on the line 158 for the five microsecond pulse length provided by oscillator 152. In the FIG. 13, waveform 156 shows information being received on 56 channels with each channel having a 5 microsecond duration followed by a synchronizing pulse 159 which is 20 microseconds wide to complete one cycle of the multiplexer of 320 microseconds of 146 followed by the next 320 microsecond cycle. This provides an effective sampling rate of about 3000 samples per second.

The output 158 is connected to a buffer amplifier 161 which provides its output on pin 3 of the connector 24. The other pins 1 and 2 of the connector 27 are connected to ground and a plus voltage respectively. The pins 1 and 2 in the connector 24 are connected to ground and a plus voltage respectively in the interface module 17.

Thus the power for the chip 86 is supplied from the interface module 17 through pins 1 and 2 of the connector 27. Pin 3 in the connector 14 receives the output signal from pin 3 of the connector 24 and supplies it through a line 164 to a demultiplexer 166. The demultiplexer 166 is provided with a plurality of output channels 167. Assuming there are 64 input channels in the multiplexer 146, there would be a corresponding number of output channels in the demultiplexer 166.

The information on the line 164 containing the synchronizing signal is also supplied through a capacitor C1 to a phase locked loop (PLL) 168 and is connected to an RC filter network 169 consisting of a resistor R5 an a capacitor C2 connected to ground. The PLL 168 is provided with an output line 172 and has provided thereon a reconstructed 200 Khz voltage controlled oscillator output which is supplied to a counter 173. The counter 173 is provided with a plurality of output lines 174 which are connected to the demultiplexer 166. The lines 174 are provided with frequencies ranging from 100 KHz to 3.125 KHz with the 3.125 KHz line 174 being connected to the phase lock loop 168 by a line 176 which serves to couple the VCO output to the phase lock loop. The use of the PLL allows the reconstruction of the 200 KHz clock, which is synchronized to the 200 KHz clock 152 in the catheter chip 86.

The demultiplexer 166 serves to demultiplex the information supplied from the multiplexer 146 and supplies it on the 56 channels 167 to circuitry 181 which includes sample and hold circuitry, filter circuitry and A-D converters to provide an output on lines 182 in the form of a signal which is supplied to the computer 31 and to the display monitor 33. The computer 31 is provided with software which has the capability of analyzing information being supplied to it by utilizing sampling techniques well known to those in the art. The computer 31 performs an analysis on the information and by use of propagation and delay time analysis identifies and isolates the area within the ventricle which may contain a re-entry pathway which may need to be ablated. This information is displayed on the screen of the monitor 33 so that it can be reviewed by the physician so that the physician can make a decision as to whether or not ablation is desirable.

Let it be assumed that re-entry pathway has been located and it is desired to ablate the same. After the mapping has been accomplished by use of the catheter or probe 22 as hereinbefore described, the same catheter or probe 22 while still in place within the ventricle may be used for accomplishing the ablation. The attending physician inputs the desired commands to the keyboard (not shown) connected to the computer 31 to give the command to proceed with an ablation. As soon as such a command is received by the computer 31, the computer 31 sends a channel number serially to pin 3 of the connector 26 which is connected to the corresponding pin 3 of the connector 23 in a serial to parallel shift register 186 which is disposed in the catheter probe 22. The shift register 186 supplies the channel number to the demultiplexer 186 on the six lines 187 to a high voltage demultiplexer 191. T he shift register 186 is provided with a clocking signal on pin 4 of the connector 23 which is supplied with a clock signal on the corresponding pin 4 of the connector 26 from the computer 31.

The output of computer 31 is also connected to a high voltage ablation power supply 196 which is programmable as to channel number and to the amount of energy to be supplied on the channel and supplies its output to pins 1 and 2 of the connector 26 which is connected to corresponding pins 1 and 2 of the connector 23 which are connected to the demultiplexer 191. The high voltage demultiplexer 191 is provided with high voltage transistors which can tolerate the ablation voltages supplied by the power supply 196. Upon command, the ablation power supply 196 supplies a high voltage, high frequency (typically 50-100 volts at 750 KHz to 1 MKz) pulse across the pins 1 and 2 of connector 26. This high voltage pulse appears on the corresponding pins 1 and 2 of the connector 23 and is supplied by the demultiplexer 191 to the appropriate charnel end appropriate electrode pair through lines 192 connected to the leads 74. This pulse appears across the electrode pair and causes an ablation to occur in the tissue of the wall of the right ventricle between the electrode pair. Alternatively, ablation can be accomplished between one of the electrode pairs and an external ground electrode placed on the chest of the patient. In this manner, it can be seen that a highly controlled ablation is provided which is precisely positioned with respect to the selected electrode pair.

Several milliseconds after the ablation pulse has been supplied to the appropriate electrode pair, mapping can again be resumed in the manner heretofore described to ascertain whether or not a re-entry pathway is still present. If the mapping indicates that at least a portion of the re-entry pathway is still present, high voltage pulses can be programmed by the computer end supplied to other appropriate electrode pairs until the re-entry pathway has been destroyed. From the pattern of the electrodes provided by the electrode array 46, it can be seen that a compact multiple electrode grid-like pattern is provided having electrode pairs precisely located throughout the entire surface of the wall of the heart forming the chamber in which the electrode array 46 is disposed so that ablation can be precisely controlled.

Programmed stimulation can be performed by using a selectable number of electrodes. In this mode of operation the interface 29 provides a programmable level of low voltage pulses (5-10 volts) via the high voltage line to stimulate the heart with synchronized pulses in order to induce or convert an arrhythmia.

The staggered radiopaque markers 65 can be utilized to ascertain which of the arms 47 of the expandable member 46 is located closes to the anatomical point of interest in the heart cavity as for example the bundle of His. By observing this staggered relationship of the markers 65, the physician can select the signals coming from a specific arm 47 to analyze the same in the computer 31 to thereby ascertain the condition of the bundle of His.

The staggered relationship of the markers 65 also makes it possible for the attending physician to observe the amount of rotation which occurs in the expendable member 46 when it is rotated by rotation of the proximal extremity of the catheter probe 22. For example, since only five of the markers 65 are used on the right arm which are spaced circumferentially by 45° it is readily ascertainable whether rotating of 45° has occurred or more or less. If rotation of 45° has occurred, a marker 65 will be shifted to a different staggered position to the other side of the expandable member 46 which will be in registration with an arm 47. If rotation of less than 45° has occurred, the offset marker 65 will not be in alignment with one of the arms 47.

By providing an additional lumen in the catheter which is commonly accomplished in catheters and having that lumen open through a port into the right ventricle, it is possible to measure the pressure in the right ventricle during mapping or ablation. By measuring the pressure in the right ventricle, it is possible to ascertain when the ventricle is filled with blood or whether it

is being squeezed. The timing of the ablation can be such that ablation occurs when the ventricle is squeezed to its smallest size. This may be desirable because at this point there will be the best contact between the electrode array 46 and the heart wall forming the ventricle. In addition, it is desirable to carry out the ablation at this point in time because at that time that the amount of blood in the ventricle is at a minimum. Thus, more of the energy created by the ablation pulse is dissipated into the heart wall rather than into the pool of blood in the right ventricle. Also, in order to accomplish this, a pressure transducer 201 can be provided in the cylindrical member or electrode array 46 and connected to electrical wires not shown into the multiplexer 146.

In accordance with the present invention, it can be seen that catheter probe 22 can be provided with an increased number of electrodes if desired. Additional channels can be readily provided in the multiplexer 146 and demultiplexer 166. The shape of the electrode array 46 can be made so that it conforms to the wall of the heart as it expands and contracts through the entire cardiac cycle. This is made possible because of the springiness of the individual arms 47 of the expandable member 46. Intimate contact is maintained with the wall of the heart minimizing the amount of energy which is dissipated into the blood pool within the cavity of the heart during ablation.

With the catheter, system and method of the present invention, mapping and ablation procedures can be carried out within relatively short periods of time, as for example, as little as one half hour. The construction of the catheter such that it will not interfere substantially with the cardiac output of the heart.

It should be appreciated that if desired, ablation can be accomplished with a separate catheter or device. It should also be obvious that if desired the system may be used to perform a routine electrophysiology study on a patient utilizing the programmed stimulation and mapping features of system.

Another embodiment of a catheter probe incorporating the present invention is shown in FIGS. 16-20. As shown therein, the catheter probe 211 which consists of a flexible elongate tubular member 36 very similar to the flexible elongate tubular member 36 hereinbefore described in the previous embodiment.

A plurality of longitudinally end racially spaced apart sets 216 of bipolar electrodes 217 and 218 are provided beyond the distal extremity of the flexible elongate tubular member 36. Expandable means is secured to the distal extremity of the flexible elongate tubular member 36 for carrying and supporting the sets 216 of electrodes 217 and 218. In the embodiment shown in FIGS. 16-20, the expandable means takes the form of a single flexible elongate strip or element 221 formed of a suitable material such as the plastic utilized for the arms 47 in the hereinbefore described embodiment of the present invention. The single flexible elongate strip 221 is utilized which is wrapped in a spiral fashion and is movable between contracted and expanded positions. The contracted position is shown in FIG. 16 and an expanded position is shown in FIG. 19.

The flexible elongate strip 221 is provided with an outer surface 222 and an inner surface 223. The sets of electrodes 216 can be formed as multilayer electrodes 217 and 218 on the outer surface 222 in the manner hereinbefore described for the previous embodiment and can have generally the same size and shape. Leads (not shown) can also be formed on the inner surface 223 in a manner similar to that hereinbefore described. The bipolar pairs of electrodes 217 and 218 are disposed longitudinally of the strip 221 or in other words in a helical direction as shown. If desired, the bipolar pairs of electrodes 217 and 218 can be arranged in different manners on the strip. For example, they can be staggered so that they extend in a direction which is at right angles to the longitudinal axis of the flexible elongate member 36.

It should be appreciated that if it is desired to achieve improved voltage propagation between the bipolar electrodes, a concentric arrangement of the bipolar electrodes can be utilized. As shown in FIG. 21, each set 226 of bipolar electrodes 227 and 228 has the electrode 227 is the form of a circular disc and electrode 228 as an annulus disposed coaxially with respect to the disc 227. The electrodes 227 and 228 can be multilayered as the electrodes 67 and 68 hereinbefore described. By way of example, the electrode 227 can have a diameter of .030", the space between the electrode 227 and the ring electrode 228 .030" with the ring electrode 228 having a width of approximately .010". The sets 226 of electrodes 227 and 228 can be spaced lengthwise of the flexible elongate strip 221 so that they are spaced apart radially and longitudinally when the flexible elongate strip 221 is wrapped in the spiral manner shown in FIG. 16.

Means is provided for moving the expandable means expanded between expanded and contracted positions and consists of an elongate cylindrical tubular member 231 formed of a suitable material such as plastic having an annular recess 232 at the proximal extremity thereof, a plastic tube 233 formed of a heat-shrinkable material is shrunk over the proximal extremity of the tubular member 231 and is seated within the recess 232. It is also shrunk over the distal extremity of the mandrel 92 to secure the tubular member 231 to the mandrel 92. Another plastic or metal cylindrical tubular member 234 is provided in the form of a rounded tip. Cooperative means is provided for rotatably mounting the cylindrical tubular member 234 on the distal extremity of the cylindrical member 231 and consists of a female recess 236 formed in distal extremity of the cylindrical member 231 which is adapted to receive by a snap-in fit a male protrusion 237 on the tip member. Thus, it can be seen that there can be relative rotation between the cylindrical member 231 and the cylindrical member 234 while restraining longitudinal movement between the same. Means is provided for rotating the tip member 234 with respect to the distal extremity of the cylindrical member 231 and consists of a torque element or wire 246 which extends from the proximal extremity of the flexible elongate tubular member 36 through the hole 97 of the mandrel 92 and through a hole 247 in the cylindrical member 231 and is coupled to the tip member 234 by extending into a hole 248 in the tip member 234 and bonded therein by suitable means such as solder or an adhesive.

One of the ends of the flexible elongate strip 221 is secured to the distal extremity of the tip member 234 by suitable means such a band 251 and an adhesive. Similarly the other of the ends of the flexible elongate strip 221 is secured to the distal extremity of the mandrel 92 in a suitable manner such as clamping it under the cover 103. The torque wire 246 can be connected to the knob 117 hereinbefore described which can be utilized for rotating the torque wire 246 rather than controlling the pull wire as in the previous embodiment.

The flexible elongate strip 221 is wound on the tubular member 231 in a clockwise direction and is relatively tightly wrapped as shown in FIG. 16 to assume its contracted position. The flexible elongate strip 221 can be moved to an expanded position by rotation of the torque element or wire 246 and the tip member 234 secured thereto in a counterclockwise direction to cause the turns of the helix of the flexible strip 221 to gradually expand in a circumferential direction to an expanded position simulating a position such as that shown in FIG. 19, that it would assume within a chamber of the heart and to move the electrodes 217 and 218 carried thereby into engagement with the wall forming the chamber of the heart in which the expandable means is disposed.

The leads (not shown) on the inner surface 223 are connected to a multiplexer chip 86 provided in the distal extremity of the flexible elongate member 36 in the same manner as heretobefore described in connection with the previous embodiment. The multiplexer 86 is connected by leads to the interface module 29 and to the computer 31 in the same manner as the previously described embodiment.

The catheter probe 211 of the embodiment shown in FIG. 16 - 20 can be readily introduced into a chamber of the heart in the same manner as the embodiment of the catheter probe hereinbefore described. As soon as the distal extremity of the catheter or probe 211 is positioned within the desired cavity of the heart, the knob 121 can be rotated in the appropriate direction to cause unwinding of the spirally wrapped flexible elongate strip 221 to cause it to progressively enlarge. Rotation is continued until the enlargement is sufficient to bring the electrodes 217 and 218 carried thereby into engagement with the wall of the heart forming the chamber in which the distal extremity of the catheter or probe 211 is disposed. By applying additional rotational forces to the knob 117, the size of the spiral formed by the flexible elongate strip 221 can be increased until all or substantially all of the electrodes carried by the strip 221 are moved into engagement with the wall. Since the strip 221 is flexible, the heart can continue its normal beating pattern in moving the wall forming the chamber inwardly and outwardly. At the same time, the spacing provided between the turns of the spiral formed by the flexible elongate strip 221 permits normal substantially unimpeded blood flow in the chamber in which the catheter probe 211 is located. The springiness of the flexible elongate strip 221 permits the flexible elongate element or strip 221 to follow the muscular contractions and expansions of the heart while still maintaining the electrodes in continuous contact with the heart wall and in contact with electrical circuitry provided within the heart wall.

When the desired potential measurements have been made which will give potentials extending around the 360° of the chamber, additional potential measurements can be made by partially contracting the spirally wound flexible elongate strips 221 by rotation of the knob 117 in an opposite direction the distal extremity of the probe 211 can be rotated through a desired angle, as for example, 15°. The flexible elongate strip 221 can then again be moved to an expanded position into engagement with the heart wall and additional potential measurements made.

If thereafter, it is desired to carry out an ablation step, this can be accomplished in the manner hereinbefore described by providing a high voltage between a selected set of bipolar electrodes.

Thereafter, after the desired procedures have been carried out, the catheter probe 211 can be removed from the body by operating the knob 117 to move the flexible elongate strip 221 into its contracted position helically wrapped about the tubular member 231. The entire catheter probe 211 can then be removed in a conventional manner.

It should be appreciated that rather than providing a single flexible elongate element or strip 221, a plurality of such flexible elements or strips can be provided which are disposed adjacent to each other to form a plurality of helices. The helices can be wound into a plurality of abutting or nearly abutting helices which can be expanded and contracted in the same manner as a single helix formed from a single flexible elongate member strip 221.

From the foregoing, it can be seen that several embodiments of the present invention have been provided which can be utilized for carrying out endocardial mapping and ablation. All of the embodiments make possible the making of simultaneous measurements at many portions of the wall forming the chamber of the heart in which the catheter probe is disposed, making it possible to make simultaneous potential measurements from such portions extending through 360°. Thus, it is possible to map the entire heart wall forming the chamber in a single step without the necessity of rotating the catheter probe to several rotational positions which may be very time consuming. In addition, with such different positions it may be difficult to precisely ascertain where the measurements were made in the chamber of the heart.

All of the embodiments of the invention have the advantage that during operation of the probe within the chamber, the heart can continue its normal operation with substantially unimpeded blood flow in the chamber because of the spacing provided between expandable means carrying the electrodes. In connection with the use of the catheter probe of the present invention *in vivo* it has been found that the basket-like construction of the probe as for example as shown in FIG. 11 due to its complex geometry causes formation of thrombus on the flexible arms 47. In order to prevent or at least inhibit the formation of thrombus it has been found desirable to coat the distal extremity of the catheter probe and the basket-like or helix type construction with an anti-thrombogenic agent as for example heparin, hirudin and streptokinase containing coatings 261 (see FIG. 11) which are applied to the catheter probe prior to insertion of the catheter probe into the heart. It has been found that these anti-thrombogenic coatings prevent and at least inhibit the formation of thrombus on the arms. The coating 261 can be applied by dipping the basket assembly which can be of the type as shown in FIG. 11 or the helix type construction shown in FIG. 20 into a solution containing the anti-thrombogenic agent so that it will adhere to the exterior surface of the arms without interfering with the electrical contact being made by the electrodes carried by the arms. Such coatings 261 may be covalently bonded to the catheter probe by techniques well known to those skilled in the art to provide coatings of a few Angstroms in thickness. Such a coating after it has been applied can be cured in a suitable manner such as by air drying at room temperature.

It should be appreciated that other embodiments of the medical probe device of the present invention can be provided which include basket assemblies carrying means for reducing the formation of thrombus thereon. In this regard, a medical probe 281 is shown in FIGS. 22-28 which includes a flexible elongate tubular member or catheter shaft 282 made from any suitable material such as plastic and having proximal and distal extremities 282a and 282b. Catheter shaft 282 extends along a central longitudinal axis 283 and is provided with at least one lumen in the form of central passageway 286 extending between proximal and distal extremities 282a and 282b. Shaft 282 further includes a plurality of four longitudinally-extending additional lumens 287 spaced apart around passageway 286 (see FIG. 25).

An expandable means in the form of basket assembly 291 is carried by distal extremity 282b of catheter shaft 282. Basket assembly 291 is formed from a plurality of eight elongate members or arms 292 having proximal and distal extremities 292a and 292b and inner and outer surfaces 293 and 294. Basket assembly 291 is movable between a first or contracted position shown in dashed lines in FIG. 22, in which the basket assembly is adapted to pass through a vessel of the body into a chamber of the heart, and a second or expanded position shown in solid lines in FIG. 22, in which basket arms 292 bow outwardly so as to engage the inside of the wall of the heart. Arms 292 are circumferentially spaced apart about axis 283 at approximately 45° angles and, as shown in FIG. 22, spaces 296 are provided between arms 292 for permitting blood to flow through basket assembly 291 while it is in its expanded position in the heart.

A plurality of electrodes 297 are carried by basket assembly 291 in longitudinally and radially spaced-apart positions along the arm. More specifically, a plurality of eight electrodes 297 are carried by each arm 292 in longitudinally spaced-apart positions. The eight electrodes on each arm 292 are grouped in four pairs so as to provide a plurality of four longitudinally spaced-apart bipolar electrodes 298.

Each arm 292 is generally strip-like in conformation and is formed from a flexible elongate support member or strip 301 made from any suitable material such as metal (see FIGS. 23 and 24). More specifically, strip 301 can be made from a superelastic shape memory alloy such as Nitinol and be provided with a predetermined bowed shape. Strip 301 has a thickness of approximately 0.007 inch at its center and a reduced thickness of approximately 0.004 inch at its proximal extremity and 0.035 inch at its distal extremity. As illustrated in FIG. 23, each arm 292 further includes a flex strip 302 having electrical or lead means in the form of conductors or traces 303 made from copper or any other suitable conductive material adhered to each side thereof. Traces 303 are electrically connected to electrodes 297. An insulating layer 306 made from any suitable material such as polyimide extends longitudinally along each side of flex strip 302 and is adhered thereto by any suitable means such as an adhesive (not shown). Flex strip 302 with insulating layers 306 thereon extends in juxtaposition to metal strip 301 and is secured thereto by an encapsulating sleeve 307 made from polyethylene terephthalate (PET) or any other suitable material. The sleeve 307 is heat shrunk around flex strip 302, insulating layers 306 and metal strip 301.

Means is included within probe 281 for securing proximal extremities 292a of arms 292 in circumferentially spaced-apart positions about distal extremity 282b of catheter shaft 282 (see FIG. 24). In this regard, medical probe 281 is provided with a tubular inner bushing 308 made from a stainless steel hypotube or any other suitable material. Bushing 308 has proximal and distal extremities 308a and 308b. Proximal extremity 308a is press fit within the distal end of passageway 286 and is provided with a plurality of circumferentially-extending slots 311 therein for providing a mechanical lock between the bushing 308 and the soft plastic material of catheter shaft 282. Inner bushing 308 is further secured within catheter shaft 282 by an epoxy 312 disposed within slots 311 and engaging the inside of passageway 286. Intermediate and outer bushings 313 and 314, each made from a stainless steel hypotube or other suitable material, extend concentrically around distal extremity 308b of inner bushing 308. Arm proximal extremities 292a extend longitudinally along the outside of outer bushing 314. Metal strips 301 of arms 292 extend with an interference fit between bushings 303, 313 and 314 so as to secure arm proximal extremities 292a to catheter shaft 282. More specifically, the proximal ends of strips 301 for four of the arms 292 circumferentially spaced approximately 90° relative to each other extend between inner and intermediate bushings 308 and 313 while strips 301 for the other four arms extend between intermediate and outer bushings 313 and 314. In this manner, strips 301 of adjacent arms 292 alternate from extending between bushings 308 and 313 and bushings 313 and 314. An adhesive (not shown) is further provided between and around bushings 308, 313 and 314 for further securing the arms 292 to catheter shaft 282.

Flex strips 302 with traces 303 thereon extend longitudinally in a proximal direction from arm proximal extremities 282a as shown in FIG. 24. Lead or electrical means in the form of eight cables 316 extend through lumens 287 of catheter shaft 282, two cables 316 in each lumen 287 as illustrated in FIGS. 24 and 25. Each cable 316 includes a plurality of at least eight conductive filaments or conductors 317. The distal ends of cables 316 are respectively secured to the proximal ends of flex strips 302 and the conductors 317 of each such cable 316 are respectively connected to the traces 303 of each such flex strip 302. Nylon thread

321 extends circumferentially around the outside of flex strips 302 for binding them together and to inner bushing 308. An encapsulant made from any suitable material such as epoxy extends circumferentially around inner bushing 308 on both sides of the proximal ends of flex strips 302 and the distal ends of cables 316 secured thereto for providing a flexible body 322 which extends distally of catheter shaft 282 to proximal extremities 292a of arms 292. Inner bushing 308 provides rigidity to body 322 at the connection of traces 303 and conductors 317. Body 322 thus acts as a rigid insulator around the electrical connection of traces 303 and conductors 317 so as to minimize shorts therebetween and further secures arms 292 to distal extremity 282b of catheter shaft 282. Body 322 is relatively flexible as it extends distally of bushing 308 about arms 292. Cables 316 extend proximally through catheter shaft lumens 287 to a pin connector 323 secured to proximal extremity 282a of the catheter shaft 282. The pin connector 323 is electrically coupled to a controller 324 which includes a computer and a power supply for generating radio frequency energy.

Arms 292 extend distally of catheter shaft 282 so that adjacent arms 292 extend at an acute angle relative to each other. Arm distal extremities 292b are joined together as shown in FIGS. 26-28 so that adjacent distal extremities 292b meet at an acute angle relative to each other. First and second plate members 331 and 332 are provided and are disposed at a substantially right angle to central longitudinal axis 283 in juxtaposition to each other. Plate members 331 and 332 are secured together by any suitable means such as an adhesive (not shown) to form a disk 333 having a circumferentially-extending outer surface 334 and generally planar proximal and distal surfaces 336 and 337. Disk 333 has a diameter of approximately 0.11 inch and a thickness of approximately 0.006 inch. Disk 333 is provided with a plurality of four first slots 338 and a plurality of four second slots 339 extending between surfaces 336 and 337. Slots 338 and 339 each have a cross-sectional size and shape slightly larger than the cross-section of metal strips 301. Each of first and second slots 338 and 339 is disposed generally at a right angle to a radius of disk 333. First slots 338 are each spaced a distance of approximately 0.04 inch from the center of disk 333 and spaced around the disk 333 at approximately 90° intervals. Each of second slots 339 is spaced a distance of approximately 0.03 inch from the center of disk 333 so as to be disposed inside first slots 338. The second slots 339 are spaced apart around disk 333 at approximately 90° intervals and are angularly offset from first slots 338 by approximately 45° (see FIG. 28). Arm distal extremities 292b are each provided with a significant bend 346 so as to provide a distal stub 347 which extends through one of slots 338 or 339. Bends 346 are facilitated by the reduced thickness of metal strips 301 at their distal extremities. An enlarged tig weld 348 is provided on the end of each distal stub 347 for retaining the stubs 347 within slots 338 and 339. A thread 349 made from nylon or any other suitable material is wrapped and secured around stubs 347 between bends 346 and disk 333 for reasons discussed below.

Basket assembly 291 of medical probe 281 is provided with a soft tip 356 secured to the joined distal extremities 292b of arms 292 (see FIG. 27). Tip 356 is formed from any suitable elastomeric and soft material such as silicone 357 which generally encapsulates disk 333 and stubs 347. The tip 356 is provided with a rounded distal end 358. A spring 359 is attached to disk 333 and extends longitudinally from both surfaces 336 and 337 thereof for providing a secure connection between the silicone 357 and the disk 333. A central bore 361 extends through surfaces 336 and 337 of disk 333 for receiving spring 359. The internal diameter of bore 361 is slightly smaller than the external diameter of spring 359 so that when the spring 359 is screwed into the bore 361 a relatively rigid connection is provided therebetween. Tip 356 is formed by inverting basket assembly 291 and placing disk 333 within a mold after the disk has been brushed with a primer to enhance adhesion. The silicone 357 is then poured into the mold and allowed to dry. The silicone material 357 extends in and around spring 359. Thread 349 around stubs 347 precludes the portions of stubs 347 extending distally of disk 333 from puncturing the silicone material of tip 356 when basket assembly 291 is contracted.

Means is carried by basket assembly 291 for inhibiting the formation of thrombus thereon when the basket assembly is disposed within the chamber of the heart. In this regard, a suitable elastomeric potting compound or coating 366 such as tecoflex polyurethane encapsulates the silicone material 357 of tip 356 and, by doing so, is disposed within pocket or cavity 367 formed by silicone 357 on proximal surface 336 of disk 333 and distal extremities 292b of arms 292 (see FIGS. 26 and 27). Coating or fill 366 is formed so as to provide a smooth arcuate surface 368 which extends between inner surfaces 293 of arm distal extremities

292b when the arms 292 are in their expanded or bowed position. Fill 366 further provides a smooth transition between the silicone 357 on outer surface 334 of disk 333 and the outer surfaces 294 of arms 292.

The means of medical device 281 for reducing the formation of thrombus on basket assembly 291 further includes proximal and distal webbings 371 and 372 carried by the basket assembly 291 (see FIG. 22). Webbings 371 and 372 are made from any suitable elastomeric and durable material such as tecoflex polyurethane. Proximal extremities 292a of adjacent basket arms 292 come together to form a vee 373 therebetween. Similarly, distal extremities 292b of adjacent arms 292 come together at disk 333 to form a vee 374 therebetween. Thus, a plurality of eight proximal vees 373 and eight distal vees 374 are provided by basket assembly 291. A webbing 371 is formed in each proximal vee 373 and includes a concave arcuate surface 378 which extends between the adjacent arms 292. Similarly, a webbing 372 is disposed within each distal vee 374 and is formed with a concave arcuate surface 379 which extends between adjacent arms. Webbings 371 and 372 are preferably sized so that the distance between the center of respective arcuate surface 378 or 379 and the bottom of respective vee 373 or 374 ranges from approximately 0.010 to 0.050 inch. The webbings 371 and 372 have a thickness not greater than approximately 0.010 inch. The material of webbings 371 and 372 is more flexible than the material of tip 356 so as to permit the expansion and contraction of basket assembly 291 as discussed above. Webbings 371 and 372 each have a thickness of not greater than 0.01 inch.

The distal extremity of catheter probe 281 and the basket assembly 291 is coated with an anti-thrombogenic agent as for example heparin, hirudin and streptokinase containing coatings 381 prior to insertion of the catheter probe into the heart for further inhibiting the formation of thrombus thereon (see FIG. 23). Coating 381 is applied to probe 283 prior to its insertion into the heart and the coating adheres to the exterior surface of the probe without interfering with the electrical contacts being made by electrodes 297. The coating 381 has a thickness ranging from a few Angstroms to approximately 0.001 inch.

The operation and use of medical probe 281 is similar to the operation and use of the medical probes discussed above. Bipolar electrodes 298 carried by basket assembly 291 can be used for sensing electrical signals from the wall of the heart so as to locate the origin of an arrhythmia. For example, basket assembly can be introduced by an introducer catheter (not shown) through a vessel of the body into the right ventricle of the heart. Once the basket assembly 291 is within the ventricle and tip 356 is engaging the apex of the ventricle, the introducer catheter is retracted relative to medical probe 281 so as to permit arms 292 to bow outwardly and basket assembly 291 to move to its expanded position. The reduced thicknesses at the proximal and distal extremities of metal strips 301 inhibit the arms 292 from buckling in the center while engaging the heart wall. The bowing of arms 282 causes electrodes 297 carried thereby to engage the wall of the heart. Signals from the endocardium are detected by bipolar electrodes 298 and transmitted via pin connector 323 to controller 324 which generates a map of the endocardium for facilitating location of the arrhythmia. Should it be desirable to ablate the endocardium, radio frequency energy can be supplied by controller 324 to one or more of electrodes 297 for creating lesions in the endocardium. It should also be appreciated that medical probe 281 can be used solely for detecting electrical signals from the endocardium and be within the scope of the present invention. In this case, any ablation of the heart wall can be performed by a separate catheter introduced into the ventricle through open probe passageway 286 or otherwise.

When basket assembly 291 is so disposed within the right ventricle or other chamber of the heart, soft tip 356 serves to provide an atraumatic contact point for deploying and holding basket assembly 291 at the apex of the ventricle. The soft silicone material of tip 356 inhibits the creation of trauma at the ventricle apex during operation of basket assembly 291.

The construction of medical probe 281 minimizes if not eliminates the formation of thrombus on the basket assembly 291 by eliminating acute angles and smoothing out edges at the joined proximal extremities 292a and joined distal extremities 292b of arms 292. Distal fill 366 inhibits blood from clotting within cavity 367 at the distal extremity of basket assembly 291 by minimizing areas around cavity 367 where blood can stagnate and thus coagulate. In a similar manner, proximal and distal webbings 371 and 372 inhibit thrombus from forming at the proximal and distal extremities of arms 292, specifically within proximal and distal vees 373 and 374.

Although medical probe 281 has been illustrated and described as having webbings provided at the proximal and distal extremities of basket assembly 291, it should be appreciated that a basket assembly having such webbing between adjacent arms at only its distal extremity can be provided and be within the scope of the present invention. Alternatively, a basket assembly can also be provided in which webbing is provided only at the proximal extremity between adjacent arms. Furthermore, it should be appreciated that webbing could be provided only between certain arms or between other adjoining members of an expandable means and be within the scope of the present invention.

In another embodiment of the invention, a catheter probe 391 is provided which is similar in many respects to catheter probe 281. The proximal extremity of probe 391 is identical to the proximal extremity of probe 281. The distal extremity of probe 391 is illustrated in FIGS. 29-32 where like reference numerals are used to identify like components of probes 281 and 391. Catheter probe 391 includes an expandable means in the form of asymmetric basket assembly 392 secured to distal extremity 282b of torquable catheter shaft 282. Basket assembly 392 is formed from a plurality of eight arms. More specifically, the basket assembly 392 includes at least one and as shown two support arms 393 having proximal and distal extremities 393a and 393b and between three and six and as illustrated six mapping arms 396 having proximal and distal extremities 396a and 396b and a central portion 396c intermediate extremities 396a and 396b. As shown more clearly in FIG. 31, arms 393 and 396 are spaced around central longitudinal axis 283 with mapping arms 396 extending along one side of axis 283 and support arms 393 being aligned about the axis 283 generally opposite to the mapping arms 396. Mapping arms 396 are spaced relatively closely together and subtend an angle of less than 180° and approximately 120° about longitudinal axis 283. The mapping arms 396 would preferably subtend an angle about axis 283 of approximately 90° for a basket assembly similar to basket assembly 392 but having only five mapping arms 396. Each arm 396 is spaced apart a distance ranging from approximately 0.2 to 0.6 inch at the longitudinal center of basket assembly 392, while support arms 393 are spaced apart a distance of approximately 0.4 to 2.4 inches at this point. Mapping arms 396 are substantially similar in construction to the arms 292 of medical probe 281. Support arms 393, as illustrated in FIG. 32, include only a flexible metal strip 397, substantially similar to metal strip 301, encapsulated by an insulating sleeve 398 substantially similar to sleeve 307.

Basket assembly 392 further includes an atraumatic tip 401 substantially similar to tip 356. Arm proximal extremities 393a and 396a are secured to distal extremity 282b of catheter shaft 282 in the same manner in which arm proximal extremities 292a of medical probe 281 are secured to catheter shaft distal extremity 282b thereof. Arm distal extremities 393b and 396b are secured to tip 401 in substantially the same manner in which arm distal extremities 282b are secured to tip 356 of medical probe 281. As so formed, basket assembly 392 is movable between contracted and expanded positions in the same manner as basket assembly 291 of medical probe 281. When in its expanded position, basket assembly 392 has a length ranging from approximately 1.5 to 3.0 inches so as to extend substantially the entire length of the chamber of the heart, as shown in FIG. 29 with respect to the right ventricle, and a diameter ranging from approximately 2.5 to 4 inches at its longitudinal midpoint.

A plurality of electrodes 402 are carried by mapping arms 396 for permitting high density mapping of regions of the endocardium. As shown in FIG. 30, a plurality of eight electrodes 402 are provided on the mapping region or sector of each mapping arm 396. These electrodes are disposed in pairs so as to form four bipolar electrodes 403 longitudinally spaced apart along the length of the arm 396.

Catheter probe 391 includes means for inhibiting the formation of thrombus thereon. In this regard, proximal webbings 404 substantially similar to proximal webbings 371 are provided in the crevices or vees 406 between adjacent arm proximal extremities 393a and 396a and distal webbings 407 substantially similar to distal webbings 372 are provided in the vees 408 formed by adjacent arm distal extremities 393b and 396b. Since the angle between adjacent mapping arms 396 is more severe and acute than the angles between arms 292 of basket assembly 291, webbings 404 and 407 extend longitudinally a distance of up to approximately 0.4 inch from the bottom of the respective vee 406 or 408. Distal fill 409 substantially similar to fill 366 described above is provided on the underside of tip 401. In addition, the distal extremity of catheter probe 391 and basket assembly 392 can be dipped or otherwise coated with an anti-thrombogenic coating 411 substantially similar to coating 381 described above.

In operation and use, asymmetric basket assembly 392 is introduced into a chamber of the heart such as the right ventricle 412 of the heart extending below valve 413 and formed by heart wall 414 in the same manner as discussed above with respect to basket assembly 291 of medical probe 281. Once within ventricle 412, basket assembly 392 is permitted to expand so that support and mapping arms 393 and 396 engage the wall of the heart. Since basket assembly 392 is generally wider than the ventricle, support arms 393 serve to urge mapping arms 396 against a portion of the heart wall so as to stabilize the basket assembly within the ventricle and provide good contact between electrodes 402 and the endocardium. The relatively close spacing between mapping arms 396 and the bipolar electrodes 403 carried thereby permit a high density map to be created from the electrical signals detected by electrodes 402. It should be appreciated that the spacing between mapping arms 396 contributes to the density of the map permitted by the basket assembly. As such, the number of mapping arms can be increased and/or the spacing between mapping arms decreased for creating higher density maps. Furthermore, a greater number of electrodes 401, for example sixteen, can be provided on each mapping arm 396 for further enhancing the definition of the endocardial map created by medical apparatus or probe 391.

The positioning of the electrodes 402 along the full length of arms 396 permits high density mapping of a "longitude" of the endocardium. Should mapping of another longitudinal portion of the endocardium be desired, basket assembly 392 can be contracted in a manner discussed above and rotated to another position before being expanded again for engaging the heart wall at this other longitudinal portion.

Webbings 404 and 407 and coating 411 are particularly desirable in basket assembly 392 because of the small angles created between mapping arms 396 where they join at tip 401 and at catheter shaft distal extremity 282b. It should be appreciated, however, that an asymmetric basket assembly 392 without webbings 404 and 407, distal fill 409 and/or coating 411 can be provided and be within the scope of the present invention. Furthermore, although electrodes 402 have been described as being arranged in the mapping sector of basket assembly 392 so as to create bipolar electrodes 403, it should be appreciated that unipolar electrodes can be provided on each mapping arm 396 and be within the scope of the present invention. It is preferable that the electrodes 402 in the mapping sector be arranged so as to be radially and longitudinally spaced apart a distance ranging from approximately 0.2 to 0.4 inch.

Electrodes 402 can be used for ablating the endocardium or a separate ablation electrode can be introduced into the chamber through central passageway 286 of catheter shaft 282 or otherwise.

Asymmetric basket assemblies substantially similar to basket assembly 392 can be provided with other arrays or patterns of mapping electrodes thereon. For example, a basket assembly 421 substantially similar in size, shape and construction to basket assembly 392 and secured to distal extremity 282b of catheter shaft 282 is shown in FIG. 33. Like reference numerals are used in describing like components of basket assemblies 421 and 392. A plurality of eight electrodes 422 arranged in four pairs of closely spaced-apart bipolar electrodes 423 are disposed on distal extremity 396b of each mapping arm 396. In another embodiment of an asymmetric basket assembly, basket assembly 426 substantially similar in size, shape and construction to basket assembly 392 and secured to distal extremity 282b of catheter shaft 282 is shown in FIG. 34. Like reference numerals are again used in identifying like components between basket assemblies 426 and 392. Basket assembly 426 includes a plurality of eight unipolar electrodes 427 longitudinally spaced apart at equal intervals on central portion 396c in relatively close spaced-apart positions. The electrodes 427 on adjacent arms are longitudinally offset relative to each other. In yet a further embodiment, an asymmetric basket assembly 431 substantially similar in size, shape and construction to basket assembly 392 and secured to distal extremity 282b of catheter shaft 282 is shown in FIG. 35. Again, like reference numerals have been used to describe like components between basket assemblies 431 and 392. In basket assembly 431, a plurality of closely spaced-apart mapping electrodes are carried by proximal extremities 396a of each mapping arm 396. More specifically, a plurality of eight electrodes 432 grouped in pairs of four bipolar electrodes 433 are carried by each arm proximal extremity 396a. It should be appreciated that more than eight electrodes can be provided on each mapping arm of basket assemblies 421, 426 and 431 and be within the scope of the present invention.

In operation and use, basket assemblies 421, 426 and 431 can be introduced into ventricle 412 or another chamber of the heart in substantially the same manner as basket assembly 392 for permitting high density mapping and/or ablation of a portion of the endocardium. Basket assemblies 421, 426 and 431 differ from basket assembly 392 in that they provide a higher density of electrodes 402 in a particular sector on mapping arms 396 so as to permit a more complete map of a particular region of the heart wall. The offset configuration of basket assembly 426 is advantageous as it minimizes zones between electrodes where information cannot be detected, for example, in the center of a square having corners defined by four nonoffset electrodes. As such, basket assembly 426 can provide a map with greater detail.

The asymmetric basket assembly previously described can have other conformations and be within the scope of the present invention. In this regard, a basket assembly 434 substantially similar to basket assembly 392 and secured to distal extremity 282b of torquable catheter shaft 282 in the same manner as discussed above is illustrated in FIGS. 36-38. Like reference numerals are used to describe like components of basket assemblies 434 and 392. Basket assembly 434 extends along central longitudinal axis 436 and includes at least one and as illustrated a plurality of two support arms 437 having proximal and distal extremities 437a and 437b. The basket assembly 434 also includes six mapping arms 438 having proximal and distal extremities 438a and 438b and a central portion 438c between extremities 438a and 438b. Arms 437 and 438 have the same respective construction of support and mapping arms 393 and 396 of basket assembly 392 and are secured at their proximal extremities to catheter shaft distal extremity 282b and at their distal extremities to an atraumatic tip 439 substantially similar to tip 401. Support and mapping arms 437 and 438 are aligned relatively opposite to each other about longitudinal axis 436. More specifically, mapping arms 438 subtend an angle about axis 436 of less than 180° and more specifically approximately 90°. As such, arms 438 are spaced apart a distance ranging from approximately 0.4 to 0.6 inch at their point of widest separation. Basket assembly 434 further includes an atraumatic tip 401 and is movable between contracted and expanded positions in the same manner as basket assembly 291.

When in its expanded position, as shown in FIGS. 36 and 37, basket assembly 434 has a length ranging from 0.5 to 1.6 inches so as to be substantially shorter than the longitudinal dimension of the heart chamber in which it is utilized. Basket assembly 434 has a diameter at its widest point ranging from 2.0 to 3.5 inches when in its expanded position and is thus provided with a transverse dimension which is greater than the widest point of the heart chamber in which it is to be introduced. This short and wide configuration of basket assembly 434 is permitted by metal strip 301 provided within each mapping arm 438 and the similar metal strip 397 provided within each support arms 437. As discussed above, strips 301 and 397 are made from any suitable flexible material such as superelastic Nitinol and are formed with a bowed shape corresponding to that of the expanded basket assembly 434. The strips 301 and 397 can be deformed, however, so as to permit basket assembly 434 to assume a contracted position similar to the contracted position shown in FIG. 22 with respect to basket assembly 291 for introducing the basket assembly into the heart.

A plurality of electrodes 441 are carried by mapping arms 438. These electrodes 441 are preferably disposed on central portion 438c of the mapping arms 438 in a manner similar to electrodes 427 of basket assembly 426 shown in FIG. 34. More specifically, a plurality of at least eight electrodes 441 are provided on each mapping arm 438. These electrodes 441 are arranged in pairs of four bipolar electrodes 442 which are spaced relatively closely together on arm central portions 396c.

Basket assembly 434 includes means for inhibiting the formation of thrombus thereon. This means includes proximal webbings 443 substantially similar to proximal webbings 404 described above and disposed within the vees 444 formed where adjacent arm proximal extremities 437a and/or 438a come together. Distal webbings 446 substantially similar to distal webbings 407 described above are provided in the vees 447 created where adjacent arms distal extremities 437b and/or 438b come together at tip 439. A fill 448 substantially similar to fill 366 is provided on the underside of tip 439 for providing a smooth transition between the distal extremities of arms 437 and 438. In addition, a coating 451 substantially similar to coating 381 is provided on the distal extremity of the catheter probe and on basket assembly 434. A portion of coating 451 is shown in FIG. 37.

In operation and use, basket assembly 434 is introduced into a chamber of the heart such as right ventricle 412 in substantially the same manner as discussed above with respect to basket assembly 291 of medical probe 281. Unlike the previously described

basket assemblies, however, basket assembly 434 does not extend substantially along the full length of the ventricle. Instead, basket assembly 434 can be positioned longitudinally at a desired location or latitude in the ventricle before being permitted to expand outwardly to its oblong configuration. Once so expanded, support arms 437 urge bipolar electrodes 442 carried by mapping arms 438 against a portion of the endocardium. The relatively close spacing between mapping arms 438 and the relatively high density of electrodes 441 carried on central portions 438c thereof permit a high density map to be created from the electrical impulses detected by the electrodes.

Should it be desirable to obtain high density maps of other regions within the ventricle or chamber of the heart, basket assembly 434 can be contracted and moved to this other location. In this regard, the basket assembly 434 can be rotated about its longitudinal axis for permitting sensing of other circumferential regions at this same longitudinal position in the chamber. In addition, basket assembly 434 can be moved upwardly or downwardly within the chamber for permitting sensing of electrical impulses at other longitudinal regions of the chamber.

Basket assembly 434 is particularly desirable as it permits high density mapping with a single catheter at a significant number of longitudinal and circumferential positions within a chamber of the heart. Webbings 443 and 446, fill 448 and coating 451 inhibit blood within the heart from clotting at the vees, cavities and other possible points on basket assembly 434 where blood may tend to stagnate.

It has also been found that a relatively short and fat basket assembly such as basket assembly 434 is advantageous because it can accommodate a greater variety of heart chamber sizes. For example, when basket assembly 434 is disposed in a chamber which is transversely sized smaller than basket assembly 434, the inward compression of arms 437 and 438 merely causes the basket assembly to extend longitudinally within the chamber.

A further embodiment of the asymmetric basket-like assembly of the present invention is illustrated in FIGS. 39-50. Medical or catheter probe 501 shown therein includes a flexible elongate tubular member or catheter shaft 502 made from any suitable material such as plastic. Catheter shaft 502 is 8.5 to 9 French in size and extends along longitudinal axis 503 between proximal and distal extremities 502a and 502b.

An expandable means in the form of an asymmetric basket-like assembly 507 is carried by distal extremity 502b of the catheter shaft 502 (see FIGS. 39 and 40). The expandable means or sector basket 507 is formed from a plurality of at least three, preferably at least four and more preferably as shown five longitudinally-extending spaced-apart members or arms 511 having proximal and distal extremities 511a and 511b. Sector basket arms 511 are movable between a first or contracted position in which arms 511 collapse and extend generally along longitudinal axis 503 and a second or expanded position in which the arms bow outwardly along one side of longitudinal axis 503. Arms 511 are shown in several expanded positions in FIG. 39. When in the contracted or compressed position, arms 511 are adapted to pass through a vessel of the human body into a chamber of the heart. In the expanded or bowed position, arms 511 are adapted for engaging the inside of the wall of the heart.

Sector basket arms 511 are asymmetrically spaced relatively closely together about longitudinal axis 503 in a group. The arms 511 subtend an angle ranging from approximately 60° to 180° about axis 503 and, more specifically as shown in FIG. 40, an angle of approximately 120° about the axis 503 so as to occupy approximately one quadrant of the circumference. As such, adjacent arms 511 of sector basket are angularly spaced apart by an angle of approximately 30°.

A plurality of electrodes 512 are carried by sector basket 507 in longitudinally and radially spaced-apart positions on the basket 507. As shown in FIG. 39, a plurality of at least eight electrodes 512 and preferably at least ten electrodes 512 are carried by each of arms 511. Electrodes 512 are grouped in five pairs on arms 511 so as to provide a plurality of five longitudinally spaced-apart bipolar electrodes 513 on each of the arms 511.

Each of arms 511 is substantially similar to arms 292 of medical probe 281 described above. More specifically and as shown in FIG. 42, each arm 511 is generally strip-like in conformation and has opposite outer and inner planar surfaces 516 and 517. Electrodes 512 are carried on the outer surface 516. Each of the arms has a predetermined bowed shape, as shown by the solid lines in FIG. 39, provided by a spring-like support member or strip 518 extending longitudinally therethrough. Strip

518 can be made from a superelastic shape memory alloy such as Nitinol or, alternatively, any other suitable material such as stainless steel. Each arm further includes a flex strip 519 having electrical or lead means in the form of conductors or traces 521 made from copper or any other suitable conductive material adhered to each of outer and inner planar surfaces 522 and 523 of the flex strip. Traces 521 are electrically connected to electrodes 512. An insulating layer 524 made from any suitable material such as polyimide extends longitudinally along each side of flex strip 519 and is adhered thereto by any suitable means such as an adhesive (not shown). Flex strip 519 with insulating layers 524 thereon extends in juxtaposition to metal strip 518 and is secured thereto by an encapsulating sleeve 526 made from polyethylene terephthalate (PET) or any other suitable material. The sleeve 526 is heat shrunk around the flex strip 519, the insulating layers 524 and the metal strip 518.

A plurality of radiopaque markers 514 are provided on sector basket 507. Markers 514 are arranged in a pattern which corresponds to the pattern of effective or bipolar electrodes 513. Specifically, a marker 514 is provided in close proximity to each of electrodes 513 so that a one-to-one relationship exists between electrodes 513 and markers 514. It is important that the spacial relationship between each electrode 513 and corresponding marker 514 be identical. In catheter probe 501, a marker 514 is provided between each of the two electrodes 512 for each bipolar electrode 513. For simplicity, only several of these markers are shown in FIG. 39. An additional set of radiopaque markers (not shown) are mounted on the arms 511 in a helical-like array as discussed above for facilitating the location of the arms 511 in the heart chamber.

Means is included within catheter 501 for interconnecting the proximal extremities 511a of arms 511 to the distal extremity 502b of catheter shaft 502 (see FIGS. 41, 43 and 44). A cylindrical binder assembly or brace 527 is carried by distal extremity 502b for receiving strips 518 of arms 511. Proximal brace 527 is formed from a plurality of eight planar disks 531 made from stainless steel or any other suitable material. Each of disks 531 has a diameter of approximately 0.1 inch and a thickness of approximately 0.015 inch. Disks 531 are each formed with a plurality of circumferentially spaced-apart slots which are longitudinally aligned with each other when disks are stacked together as shown in FIG. 41. First linear slot 532a is centered and perpendicular to a radius of disk 531 and is located approximately 0.03 inch from the center of the disk. The two second linear slots 532b are formed diametrically outside first slot 532a and are inclined at an oblique angle of approximately 30° relative to the first slot 532a. The second slots 532b are symmetrically aligned relative to a diameter extending perpendicularly through the center of the first slot 532a. Two third linear slots 532c are spaced circumferentially from first slot 532a on respective opposite sides thereof and are each aligned at an oblique angle of approximately 60° relative to first slot 532a. Second and third slots 532b and 532c extend through the outer cylindrical surface 533 of disk 531. The proximal ends of strips 518 extend through respective slots 532 and are precluded from being removed therefrom by a tig weld 536 formed on the proximal end of each strip 518 proximal of brace 527. Encapsulating sleeves 526 terminates at catheter shaft distal extremity 502b to permit separation of strips 518 from flex circuits 519 at proximal brace 527.

Flex circuits 519 of arms 511 extend along the outer cylindrical surface 533 of proximal brace 527 in circumferentially spaced-apart positions and terminate at a location proximal of the brace 527 (see FIGS. 41 and 43). An electrical or conductor means in the form of a ten conductor cable 541 is electrically connected by solder joints (not shown) or any other suitable means to traces 521 carried by each flex circuit 519. As shown most clearly in FIG. 41, five of the separately insulated conductors 541a of a cable 541 are electrically connected to respective traces 521 on the inner surface 523 of the flex circuit 519. The traces 521 on outer surface 522 of flex circuit 519 extend proximally beyond the traces on the inner surface 523 of the flex circuits. A hole (not shown) is etched through the flex circuit to permit access to the outer surface traces 521 from the inner surface 523. The second five conductors 541b of the cable 541 are electrically connected at their distal ends to the outer surface traces 521. A short tubular member in the form of sleeve 542 made from PET or any other suitable material, shown in FIG. 44 but not FIG. 41, is heat shrunk around the joined portions of flex circuits 519 and cables 541 to prevent electrical short circuits between the flex circuits 591. An epoxy (not shown) extends around each end of sleeve 542 to provide a fluid seal for the solder joints.

Distal extremity 502b of catheter shaft 502 includes a proximal section 546, a central or highly flexible section 547 and a distal section 548 (see FIGS 39 and 41). Proximal brace 527 is a part of distal section 548. Sections 547 and 548 have respective

lengths of approximately 0.8 inch and 0.6 inch. Proximal section 546 is formed from a tubular member 551 made from any suitable flexible plastic such as Pebax having a durometer of approximately 72. Highly flexible section 547 is formed from a tubular member 552 made of highly flexible plastic material such as Pebax having a durometer of approximately 45. Each of tubular members 551 and 552 is formed with at least one and as shown three lumens extending longitudinally therethrough (see FIGS. 46 and 47). Specifically, tubular member 551 is provided with a central lumen 556 and first and second diametrically opposite peripheral lumens 557 and 558. Similarly, tubular member 552 is provided with a central lumen 561 and first and second diametrically opposite peripheral lumens 562 and 563 communicating respectively with lumens 556, 557 and 558 of tubular member 551. Tubular member 551, which extends to the proximal end of catheter shaft 502, is fused with heat or otherwise suitably secured to tubular member 552.

A tubular sleeve 566 made from any suitable material such as Pebax having a durometer ranging from 63 to 72 extends around tubular member 551 along the length thereof (see FIG. 41 and 47). Sleeve 566 has a flat braid 567 made from stainless steel or any other suitable material embedded therein for providing torsional rigidity to proximal section 546. Similarly, a tubular sleeve 568 made from any suitable material such as Pebax and having a durometer ranging from 35 to 45 extends around tubular member 552 along the length thereof (see FIG. 41 and 46). Sleeve 568 also serves to provide torsional rigidity to catheter shaft 502 and has a round braid 569 made from any suitable material such as stainless steel embedded therein.

A substantially rigid plastic tube 571 made from braided polyimide or any other suitable material and formed with a central bore 572 extending longitudinally therethrough is included within the means for securing proximal brace 527 to highly flexible section 547 of the catheter shaft 502 (see FIGS. 41 and 43-46). The proximal end of tube 571 is secured by an adhesive (not shown) or any other suitable means within the distal end of lumen 557 of proximal section 546. Binder disks 531 are each provided with an offset bore 573 extending therethrough in general diametric alignment with first slots 532a for receiving the distal end of tube 571. The tube 571 secured by an adhesive (not shown) or any other suitable means within bore 573 and further serves to retain disks 531 in proper relative alignment. The substantially rigid distal section 548 is further formed from an encapsulant 574 made from any suitable flexible epoxy adhesive such as DP 190 made from 3M Corporation of Minneapolis, Minnesota. Cables 541 extend proximally from flex circuits 519 through central lumen 561 of highly flexible section 547 and central lumen 556 of proximal section 546 to the proximal end of catheter shaft 502 (see FIGS. 46 and 47). First lumens 557 and 562 and bores 573 and 572 serve to form a passageway 576 which extends from the shaft proximal extremity 511a to an opening 577 at the shaft distal extremity 511b as shown in FIG. 39.

Means which includes atraumatic tip 579 is provided for interconnecting distal extremities 511b of arms 511 in a manner similar to that described above with respect to medical probe 281 (see FIGS. 39, 48 and 49). Tip 579 has a distal binder assembly or brace 581 similar to proximal brace 527. Brace 581 is constructed from first and second plate members or disks 582. Each of disks 582 has a diameter of approximately 0.11 inch and a thickness of approximately 0.006 inch. A plurality of slots 583 extend between the top and bottom planar surfaces of each disk 582. Specifically and as shown in FIG. 49, first, second and third slots 583a, 583b and 583c are provided. Slots 583a, 583b and 583c are sized and aligned similar to slots 532a, 532b and 532c. However, unlike second and third slots 532b and 532c in disks 531, second and third slots 583b and 583c in disks 582 do not extend through outer cylindrical surface, that is surface 586, of disks 582. A suitable adhesive (not shown) serves to secure the disks 582 together. The distal extremities 511b of arms 511 extend beyond encapsulating sleeve 526 and each have a significant bend 591 which forms a distal stub 592 extending in a direction generally parallel to longitudinal axis 503. Stubs 592 are received by respective slots 583. An enlarged tig weld 593 is formed on the end of each distal stub 592 for retaining the stubs within disks 582.

Atraumatic tip 579 is substantially similar to tip 356 described above and has a soft, rounded distal end 601 as shown in FIG. 48. Briefly, tip 579 is formed from any suitable elastomeric and soft material such as silicone 602 which encapsulates disks 582 and stubs 592. A coating 606 made from any suitable elastomeric potting compound such as tecoflex polyurethane extends around the rounded end 601 and the distal extremities 511b of arms 511 to provide smooth transitional surfaces between

the arms 511 and tip 579. A similar potting compound also extends between arm distal extremities 511b to form distal webbings 607 which are substantially similar to distal webbings 372 described above. Coating 606 and webbings 607 serve to reduce the formation of thrombus on sector basket 507 in the same manner as coating 366 and webbings 372 described above. An additional coating 608 substantially similar to coating 381 is also applied to sector basket 507 for further inhibiting the formation of thrombus thereon (see FIGS. 42, 48 and 49).

Catheter probe 501 has push/pull means which includes push/pull wire 611 for moving arms 511 from their predetermined shape shown in solid lines in FIG. 39, to an extended or contracted position shown in phantom lines and identified by reference numeral 612 in FIG. 29, or to a fully bowed position shown in phantom lines in FIG. 39 and identified by reference numeral 613. Push/pull wire 611 has proximal and distal end portions 611a and 611b and is made from any suitable material such as a superelastic Nitinol. The wire 611 has a diameter of approximately 0.0175 inch which permits the wire to be slidably carried within passageway 576 of catheter shaft 502. The distal end portion 611b of wire 611 extends from passageway opening 577 to the interconnected distal ends of arms 511. Wire 611 has the column strength to withstand buckling when a compressive force is applied to the wire to push atraumatic tip 579 distally and thus move sector basket 507 to its extended position.

Atraumatic tip 579 is included within the means of sector basket 507 for securing wire distal end portion 611b to the interconnected distal extremities of arms 511. As shown in FIGS. 48 and 49, disks 582 are each provided with an off-center bore 616 extending through the planar surfaces thereof in diametric alignment with first slot 583a. Wire 611 extends through coatings 606 and 608 and silicone 602 before passing through bore 616. An enlarged tig weld 617 is formed on the distal end of wire 611 and precludes the wire from being pulled proximally through bore 616. A helical spring 618 is wrapped between the tig weld 617 and the upper disk 582 and extends distally of brace 581 for further securing silicone 602 to tip 579. An annular clamp 619 made from polycarbonate or any other suitable material is secured to wire 611 proximal of the lower disk 582 by any suitable means such as an adhesive (not shown). Clamp 619 secures wire distal extremity 611b to brace 581 when the wire 611 is under compression. When sector basket 507 is moved to its fully bowed position 613, arms 511 bow outwardly at their mid-point to an approximate distance of 0.8 inch from pull wire 611 and atraumatic tip 579 is spaced distally of catheter shaft 502 a distance of approximately 1.5 inch.

An additional pull wire 622 extends through catheter shaft 502 and is included with the means for bending or flexing the catheter shaft at highly flexible section 547. Pull wire 622 is made from any suitable material such as stainless steel and has proximal distal end portion 622a and 622b. A clamping or deflection ring 623 is embedded within distal section 548 for serving as means for securing wire distal end portion 622b to the distal extremity 502b of catheter shaft 502. Deflection ring 623 is made from any suitable material such as stainless steel and has a length of approximately 0.3 inch and an outer diameter of approximately 0.08 inch. The ring 623 is concentrically disposed about longitudinal axis 503 and extends around tube 571. Wire end portion 622b extends along the inside of ring 623, off-center axis 503, and is secured to the ring 623 by solder 624 or any other suitable means. Pull wire 622 extends proximally from deflection ring 623 through second lumen 563 of highly flexible section 547 and second lumen 558 of proximal section 546 (see FIGS. 46 and 47).

Handle means or handle 631 is carried by proximal extremity 502a of catheter shaft 502. Handle 631 is of the type described in U.S. Patent No. 5,478,330, incorporated herein by this reference, and includes a body 632 having a first handle member or circular knob 633 slidably mounted thereon and a second handle member or tubular sleeve 634 rotatably mounted thereon. Sleeve or rotator 634 is coupled to proximal end portion 611a of push/pull wire 611 and serves as finger actuatable means for moving wire 611 proximally or distally within catheter shaft 502. More specifically, rotation of rotator 634 about body 632 in a clockwise direction causes wire 611 to move longitudinally in a distal direction and thus causes sector basket arms 511 to contract towards longitudinal axis 503. Rotation of rotator 634 in an opposite direction moves wire 611 longitudinally in a proximal direction within the catheter shaft 502 and thus causes arms 511 to bow outwardly relative to longitudinal axis 503. Circular knob 633 is coupled to proximal end portion 622a of pull wire 622 and serves as finger actuatable means for bending sector basket 507 at highly flexible section 547 as shown in FIG. 39. In this regard, forward longitudinal movement of knob 633 on body 632 causes the sector

basket 507 to move from a position generally centered on longitudinal axis 503, shown in solid lines in FIG. 39, to a off-axis position in which the sector basket extends at an angle of approximately 45° or more relative to longitudinal axis 503, shown in phantom lines in FIG. 39.

Handle 631 includes a central lumen 637 in communication with passageway 576 in catheter shaft 502. A Y fitting 638 is secured to the proximal end of handle body 632 and has a first connector 641 in communication with handle lumen 637. Electrical cables 541 extend through handle 631 and out second connector 642 of Y fitting 638. The electrical means of catheter probe 501 further includes an electrical cord 643 which extends from second connector 641 to a pin connector 644 adapted for attachment to a controller or work station 646 which can include a radio frequency generator.

Each of electrodes 512 is generally rectangular in plan and has a length of approximately 0.030 inch and a width of approximately 0.009 inch. Electrodes 512 each have an outer wall-engaging layer 647 formed from a suitable material such as platinum black adhered to a first intermediate layer 648 formed from palladium, a second intermediate layer 649 formed from gold and a third intermediate layer 651 formed from nickel flash (see FIG. 50). Bottom intermediate layer 651 is adhered to the copper trace 521 carried by flex circuit 519. Layers 647, 648, 649 and 651 have respective thickness of approximately 50, 10, 20 and 50 micro inches. The irregular shape of the platinum black outer layer 647 provides the relatively small electrode with a relatively large surface area for receiving signals from the heart wall.

In operation and use, catheter probe 501 is introduced into the right ventricle or other chamber of the heart in the manner described above. Briefly, an introducer catheter (not shown) is inserted into the ventricle by means of a pigtail catheter or guide wire. Once the pigtail catheter or guide wire has been removed from the introducer catheter, rotator 634 is moved or rotated in a counter-clockwise direction to cause sector basket arms 511 to move to their most contracted position. Arms 511 are collapsed and inserted into the passageway of the introducer catheter and slid therethrough for introduction into the ventricle. Movement of push/pull wire 611 to its distalmost position facilitates collapsing and loading of sector basket 507 into the introducer catheter. After sector basket 511 has been deployed within the ventricle and the introducer catheter has been moved proximally to a position at least proximal of the highly flexible section 547, if not withdrawn entirely from the body, bipolar electrodes 513 carried by the sector basket 507 can be moved into engagement with a portion of the heart wall.

Push/pull wire 611 serves to retain basket arms 511 in a bowed position during engagement with the heart wall by precluding atraumatic tip 579 from moving distally or otherwise with respect to distal extremity 502b of catheter shaft 502 as arms 511 arch against the heart wall. Wire 611 further permits selective shaping of sector basket 507 by increasing the arch of arms 511 as atraumatic tip 579 is pulled proximally by the wire 611. A greater arch may be desired in arms 511 so that they better approximate the shape of the ventricle. In addition, the urging force exerted by each arm 511 against electrodes 512 carried thereby increases as the radius of the bow in each arm 511 is reduced by proximal movement of tip 579 relative to catheter shaft 502. Alternatively, the stiffness of arms 511 can be decreased by moving wire 611 distally. The resulting flexible sector basket 507 can be advantageous for mapping and/or ablating certain portions of the heart such as discussed more fully below. As can be seen, the stiffness of basket arms 511 can be selectively adjusted through proximal or distal movement of push/pull wire 611.

The deflectable distal extremity of catheter probe 501 permits sector basket 507 to be directed to different areas of the ventricle. For example, knob 633 can be pulled proximally relative to handle 631 for causing catheter shaft distal extremity 502b to bend and thus cause sector basket 507 to come into engagement with the heart wall. Highly flexible section 547 facilitates bending of distal extremity 502b at the section 547. Such bending may be particularly advantageous when mapping and/or ablation is required in the basal section of the ventricle. The deflectable distal extremity of catheter probe 501 also serves to promote better contact between electrodes 512 and the heart wall by increasing the force urging the electrodes against the heart wall.

Catheter probe 501 can be utilized for mapping the apex of a heart chamber such as a ventricle. In such a procedure, tip 579 is moved distally by wire 611 to cause arms 511 to move to their fully extended position relative to shaft 502. Arms 511 and basket 507 are very flexible in this position. Tip 579 is thus capable of being pushed across the apex of the ventricle so that arms 511 extend across the apex generally transverse thereto. With the sector basket 507 so positioned in the heart, electrodes

514 engage the heart wall at and about the apex and permit high density mapping of the apex and the heart wall therearound. The catheter probe 501 can also be used to map the basal section of the ventricle by pushing on handle 631 to cause sector basket 507 to move fully across the apex and back up the ventricle toward the aortic valve.

Once bipolar electrodes 513 are in engagement with the heart wall, signals from the endocardium are detected by the electrodes. Cables 541 permit electrical functions to be performed with respect to electrodes 513. For example, an isochronal or other map of the endocardium can be created from the signals detected by the electrodes. Should it be desirable to ablate portions of the endocardium, radio frequency energy can be supplied by the controller to one or more of the electrodes 512 for creating lesions in the endocardium.

The platinum black outer layer 647 of electrodes 512 lowers the impedance of the electrodes 512 by effectively increasing the surface area of the electrodes. More specifically, layer 647 reduces the impedance of each electrode 512 by a factor of approximately 100 to 1,000 to an approximate range of 2 to 10 kilo-ohms for the frequency range of operation. This impedance reduction is particularly desirable for the relatively small electrodes 512 and permits the electrodes to obtain higher quality signals with less background noise. It should be appreciated that the construction of electrodes 512 can be utilized for other electrodes herein and be within the scope of the present invention.

Radiopaque markers 514 permit each effective electrode or bipolar electrode 513 of sector basket 507 to be readily identified through fluoroscopy so as to facilitate identification of the basket 507 within the heart. Markers 514 also facilitate placement of any individually controllable ablation electrode relative to electrodes 513 of sector basket 507.

While sector basket 507 is disposed within the ventricle or other chamber of the heart, a heparin saline solution can be introduced through opening 577 by means of first connector 641. This flow of saline solution adjacent arm proximal extremities 511a serves to inhibit the formation of thrombus at shaft distal extremity 502b and arm proximal extremities 511a. Thrombus on sector basket 507 is further minimized by the heparin coating 608 provided on the basket and webbings 607 between distal extremities 511b of basket arms 511.

Should it be desirable to reposition sector basket 507 within the ventricle, handle 631 can be used to torque catheter shaft 507 and thus move the sector basket 507 angularly about longitudinal axis 503. Braided tubular elements 567 and 569 enhance one-to-one rotational movement between shaft proximal and distal extremities 502a and 502b. Prior to rotation, knob 633 can be moved to its distalmost position on handle 631 so as to straighten catheter shaft 502 at highly flexible section 547. In addition, atraumatic tip 579 can be moved to its distalmost position by means of push/pull wire 611 and rotator 634 for reducing the bow or arch in sector basket arms 511. Braids 567 and 569 provided in catheter shaft 502 facilitate one-to-one rotation between the proximal and distal extremities of catheter shaft 502. After said relocation of sector basket 507, knobs 633 and rotators 634 can be utilized as discussed above to desirably position basket arms 511 and bipolar electrodes 513 relative to the heart wall.

It should be appreciated that sector basket 507 can be longitudinally sized to cause it to extend longitudinally through the entire ventricle or heart chamber during use. Alternatively, basket 507 can be shorter so as to permit it to be moved longitudinally within the chamber. Arms 511 can be sized to increase or decrease the amount of bow therein. Furthermore, it should be appreciated that electrodes 512 can be grouped or clustered on basket arms 511 instead of being spaced apart as shown in FIG. 39. For example, as discussed above with respect to the embodiments shown in FIGS. 33-35, electrodes 512 can be grouped distally, equatorially or proximally on basket arms 511. Electrodes 512 can also be used for obtaining unipolar signals from the heart. As can be appreciated, for unipolar sensing and/or mapping, each unipolar electrode on the mapping catheter is an effective electrode. Accordingly, a radiopaque marker similar to marker 514 can be provided at each unipolar electrode so as to provide a one-to-one relationship between the unipolar electrodes and markers for facilitating the location of the effective or unipolar electrodes in the heart.

It has been found that catheter probe 501 and sector basket 507 thereof is particularly useful for mapping or ablating on the papillary muscles within the heart. The close grouping of basket arms 511 facilitates placement of electrodes 512 on and around these muscles.

Another embodiment of the asymmetric or sector basket of the present invention is shown in FIGS. 51-56. Catheter probe 656 therein is substantially similar to catheter probe 501 and like reference numerals are used to describe like components of catheter probe 656 and catheter probe 501. The catheter probe 656 includes a flexible elongate tubular member in the form of catheter shaft 657 having proximal and distal extremities 657a and 657b. Catheter shaft 657 has a tubular member 658 made from a suitable material such as Pebax having an outer diameter of approximately 0.12 inch. Shaft 647 extends along a central longitudinal axis 659. An expandable means in the form of an asymmetric or basket-like assembly 661 is carried by distal extremity 657b. The expandable means or sector basket 661 is substantially similar to sector basket 507 and has a plurality of five arms 511 which extend along one side of longitudinal axis 658. Arms 511 subtend an aggregate angle of approximately 90° about longitudinal axis 659.

A cylindrical binder assembly or brace 662 is included within the means of catheter probe 656 for interconnecting the proximal extremities 511a of sector basket arm 511 to distal extremity 657b of catheter shaft 657 (see FIGS. 51 and 54). Proximal brace 622 is substantially similar to proximal brace 527 described above and includes a plurality of disks 663 substantially similar to disks 531. Each of disks 663 has a first slot 532a, second slots 532b and third slots 532c formed therein for receiving strips 518 of arms 511. Second and third slots 532b and 532c are aligned at respective angles of approximately 22.5° and 45° relative to first slot 532a. The disks 663 are encased in a encapsulant 666 substantially similar to encapsulant 533 described above for forming distal section 667 of catheter shaft distal extremity 657b. Tubular member 658 is provided with at least one lumen or passageway 671 extending between proximal and distal extremities 657a and 657b. Passageway 671 has a diameter ranging from 0.085 to 0.090 inch. Cables 541 extend from distal section 667 through passageway 671, as shown in FIG. 55, to the proximal extremity of catheter shaft 657. Tubular member 658 is encased along its length by a tubular braided sleeve 672 substantially similar to tubular sleeve 566.

An atraumatic tip 676 substantially similar to tip 579 is included within the means of catheter probe 656 for securing together arm distal extremities 511b (see FIGS. 51 and 56). Tip 676 includes a distal binder assembly or brace 677 substantially similar to distal brace 581 and formed from a plurality of disks 678 substantially similar to disks 582. A first slot 583a, second slots 583b and third slots 583c are formed in each disk 678 for receiving distal stubs 592 of arms 511. Second and third slots 583b and 583c are aligned at respective angles of approximately 22.5° and 45° relative to first slot 583a.

At least one additional arm is slidably carried by catheter shaft 657 for urging sector basket 661 against the heart wall (see FIGS. 51 and 52). More specifically, first and second additional or slidable arms 681 having proximal and distal extremities 681a and 681b are included within catheter probe 656. As shown in FIG. 52, slidable arms 681 are angularly positioned about longitudinal axis 658 so as to extend along a side of axis 658 generally opposite sector basket 661. The slidable arms 681 are symmetrically spaced-apart at a separation angle ranging from 40° to 120° and preferably approximately 60°.

As shown in FIG. 53, each slidable arm 681 has a spring-like member 682 made from any suitable material such as stainless steel or superelastic Nitinol. Spring member 682 is encased within an encapsulating sleeve 683 substantially similar to sleeve 526 and is generally rectangular in cross-section so as to be formed like a strip at distal extremities 681b of arm 681. Spring members 682 are each formed with a predetermined shape so as to cause distal extremities 681b of slidable arms 681 to have an inherent bowed conformation, as shown in solid lines in FIG. 51, which approximates the bowed shape of sector basket arms 511.

Means for securing distal extremities 681b of slidable arms 681 to arm distal extremities 511b includes distal brace 677 (see FIG. 56). In this regard, each of disks 678 is provided with first and second additional slots 686 for respectively receiving the distal ends of spring members 682. Slots 686 are aligned diametrically opposite first slot 583a along opposite sides of a diameter of the disk 678 which extends perpendicularly through the first slot 583a. Each of slots 686 is symmetrically aligned at an angle of approximately 30° to said diameter. A tig weld 687 is formed at the end of each spring member 682 above disks 678 for securing the slidable arms 681 to atraumatic tip 676. An circular clamp 688 substantially similar to clamp 619 described above is secured

around the distal extremity 681b of each arm 681 below disks 678 for precluding the arms 681 from being pushed through tip 676.

Proximal brace 662 is provided with first and second additional slots 696 for slidably receiving arms 681 (see FIG. 54). Slots 696 have a similar alignment with respect to first slot 532a as additional slots 686 in disks 678 have with respect to slot 583a thereof. Slidable arms 681 extend proximally from brace 662 through encapsulant 666 and passageway 671 to the proximal extremity of catheter probe 656. Spring members 682 of the arms 681 transition from a strip-like configuration to a rounded configuration at a point proximal of catheter shaft section 667 (see FIG. 55).

Handle means in the form of handle 697 is secured to the proximal extremity 657a of catheter shaft 657 as shown in FIG. 51. Handle 697 includes an elongate body 698 made from any suitable material such as plastic. Proximal extremities 681a of slidable arm 681 extend into handle 697 and are connected to respective finger actuatable means in the form of first and second sliders 701 mounted for travel within respective slots 702 formed in handle body 698. Proximal movement of sliders 701 causes arms 681 to move to a more retracted position as shown in phantom lines in FIG. 51 and depicted by reference numeral 703 therein. Distal movement of sliders 701 cause arms 681 to move to a more bowed position as also shown in phantom lines in FIG. 51 and depicted by reference numeral 704 therein. Arms 681 have a diameter of approximately 4.72 inch at their midpoint with respect to basket arms 511 when in the bowed position identified by reference numeral 704.

A lumen 706 extends longitudinally through handle 697. Lumen 706 communicates at its distal end with passageway 671. First connector 641 of Y fitting 638 communicates with the proximal end of lumen 706 for permitting a saline solution to be introduced through lumen 706 and passageway 671. A bore 707 extends longitudinally through disks 663 and encapsulant 666 of distal section 667 of the catheter shaft 657. Bore 707 communicates with passageway 671 and has a distal opening 708 adjacent proximal extremities 511a of sector basket arms 511.

In operation and use, catheter probe 656 is introduced into a ventricle or other chamber of the heart in the same manner as discussed above. Once deployed from the introducer catheter, arms 511 of sector basket 661 bow outwardly to their predetermined shape as shown in FIG. 51. Slidable arms 681 also bow outwardly from longitudinal axis 658. In this manner, sector basket arms 511 and slidable arms 681 form a basket-like assembly within the heart. One or both of sliders 701 are then moved distally on handles 697 to cause slidable arms 681 to engage one side of the heart wall and thus cause sector basket 661 to be urged against an opposite side of the heart wall. The rectangular cross-section of arm distal extremities 681b inhibits transverse movement of the arms 681 across the heart wall. The circular cross-section of arm proximal extremities 681a inhibits the arms 681 from assuming a preferential orientation within catheter shaft 657 despite bending of the shaft 657 as it extends through the vessel of the patient.

Bipolar electrodes 513 permit a high density map to be created from a portion of the chamber wall in a manner discussed above. Should further portions of the heart wall need to be mapped, sliders 701 are moved proximally in handle slots 686 to collapse distal extremities 681b of slidable arms 681. Handle 697 can then be rotated about longitudinal axis 658 and/or moved longitudinally about axis 658 to cause sector basket 661 to move to another position within the heart chamber. Arm distal extremities 681b can be collapsed beyond their predetermined shape, as shown by reference numeral 703 in FIG. 51, to facilitate rotation of sector basket 661 within the heart.

The mapping assembly of catheter probe 656 is advantageous in many respects. Sector basket 661 can be longitudinally sized smaller than the heart chamber being mapped so as to be moveable to different longitudinal positions in the heart. The torquable catheter shaft 657 permits sector basket 661 to be positioned anywhere around the circumference of the chamber. The individually slidable arms 681 permit the sector basket 661 to achieve a stable position in an irregular-shaped heart chamber. For example, one of the slidable arms 681 may be pushed farther outwardly from longitudinal axis 658 so as to extend between papillary muscles inside the heart. The individual movement of sliders 701 and slidable arm 681 further permit the operating physician to vary the force applied across sector basket 661. As can be seen, a single catheter can thus be utilized to densely map a variety of areas within a heart chamber.

It should be appreciated that less than two or more than two slidable arms 681 can be provided in a catheter probe and be within the scope of the present invention. It should be further appreciated that slidable arms 681 can be interconnected so as to move in unison. In addition, the slidable support arms 681 can be positioned in other angular positions relative to sector basket 661 to optimize the stability of the basket 661 in the heart.

Radiopaque markers such as markers 514 can also be utilized in basket assemblies such as basket assembly 291 of medical probe 281 and be within the scope of the present invention. As discussed above and illustrated in FIGS. 22 and 26, basket assembly 291 has a plurality of arms 292 which are circumferentially spaced apart at equal angular intervals. A radiopaque marker 711 can be added to arms 292 of basket assembly 291 for each effective or bipolar electrode 298 to identify electrodes 298 through fluoroscopy. For simplicity, only two markers 711 are shown in FIG. 57.

From the foregoing, it can be seen that a new and improved medical probe device has been provided with a basket assembly which inhibits the formation of thrombus thereon. Elastomeric material has been disposed on the basket assembly at locations where blood would tend to coagulate while the basket assembly is within the heart. A webbing has been provided between adjacent arms at the proximal and/or distal extremities of the basket assembly. The basket assembly has an atraumatic tip which inhibits the creation of trauma when the basket assembly is urged against the apex of a chamber within the heart.

In addition, an asymmetrical basket-like assembly has been provided wherein certain of the arms are grouped closely together so as to permit high density mapping of regions within the heart. The asymmetrical basket-like assembly can be sized to fill substantially the entire chamber of a heart. Alternatively, the asymmetrical basket-like assembly can be sized to fill less than the entire chamber of the heart so as to permit the basket-like assembly to be moved longitudinally to different positions within the chamber. A plurality of mapping electrodes are carried by the asymmetric basket-like assembly and can be located at various positions on the group of mapping arms thereof. A push/pull wire can be included in the basket-like assembly for facilitating expansion and contraction of the arms of the assembly. The distal extremity of the probe device can be controllably flexed for placement of the basket-like assembly in the heart. Alternatively, one or more slidable support arms disposed opposite the clustered arms of the basket-like assembly can be provided for urging the clustered arms against the heart wall. Radiopaque markers can be provided on the expandable means in a pattern corresponding to the electrodes carried by the expandable means for facilitating location of the electrodes while the basket-like assembly is in the heart.

WHAT IS CLAIMED IS:

1. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities, a lumen extending along a longitudinal axis between the proximal and distal extremities, a plurality of longitudinally-extending spaced-apart arms having proximal and distal extremities, means interconnecting the proximal extremities of the arms to the distal extremity of the flexible elongate tubular member, means interconnecting the distal extremities of the arms, the arms movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis, the arms subtending an angle of approximately 180° or less about the longitudinal axis when in the expanded position, a plurality of longitudinally spaced-apart electrodes carried by each of the arms, electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes, a wire slidably carried within the lumen having proximal and distal end portions, the means interconnecting the distal extremities of the arms securing the distal end portion of the wire to the distal extremities of the arms, means carried by the proximal extremity of the flexible elongate tubular member for pulling the proximal end portion of the wire to cause the arms to move to the expanded position whereby the electrodes carried by the arms can be urged against a portion of the wall of the heart when the arms are in the expanded position to map said portion of the wall.

2. A probe as in Claim 1 wherein the arms constitute five in number.

3. A probe as in Claim 1 wherein at least ten electrodes are carried by each of the arms.

4. A probe as in Claim 1 wherein the arms each include a spring-like member extending thereamong which has a predetermined bowed shape.

5. A probe as in Claim 1 further comprising means carried by the proximal extremity of the flexible elongate tubular member for pushing the wire distally within the lumen to move the arms toward the contracted position, the wire having a column strength sufficient to prevent buckling of the wire when a compressive force is exerted thereon.

6. A probe as in Claim 1 further comprising means carried by the flexible elongate tubular member for bending the distal extremity of the flexible elongate tubular member to move the electrodes carried by the arms toward said portion of the wall.

7. A probe as in Claim 6 wherein the distal extremity of the flexible elongate tubular member includes a highly flexible portion for facilitating bending at the highly flexible portion.

8. A probe as in Claim 6 wherein the bending means includes a pull wire extending between the proximal and distal extremities of the flexible elongate tubular member.

9. A probe as in Claim 1 wherein the flexible elongate tubular member is provided with a tubular braided element for enhancing one-to-one rotational movement between the proximal and distal extremities of the flexible elongate tubular member.

10. A probe as in Claim 1 wherein the lumen extends to an opening adjacent the proximal extremities of the arms, a fitting carried by the proximal extremity of the flexible elongate tubular member in communication with the lumen for permitting a liquid to be introduced through the opening into the heart for inhibiting the formation of thrombus at the proximal extremities of the arms.

11. A probe as in Claim 1 wherein the arms subtend an angle of approximately 120° about the longitudinal axis.

12. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate member having proximal and distal extremities, a plurality of longitudinally-extending spaced-apart arms carried by the distal extremity of the flexible elongate member, means interconnecting the distal extremities of the arms, the arms movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis, the arms being asymmetrically spaced about the longitudinal axis when in the expanded position to as to be spaced relatively closely together in a group, a plurality of longitudinally spaced-apart electrodes carried by each of the arms, electrical means extending through the flexible elongate member and connected to the electrodes for performing electrical functions with respect to the electrodes and means carried by the flexible elongate member for bending the distal extremity of the flexible elongate member so as to move the arms toward a portion of the wall whereby the electrodes carried by the arms engage said portion of the wall of the heart when the arms are in the expanded position to map said portion of the wall.

13. A probe as in Claim 12 wherein the flexible elongate member is provided with a lumen extending between the proximal and distal extremities, the bending means including a pull wire extending through the lumen and having a distal end portion, means for securing the distal end portion of the pull wire to the distal extremity of the flexible elongate member.

14. A probe as in Claim 12 further comprising a handle carried by the proximal extremity of the flexible elongate member, finger actuatable means carried by the handle for moving the pull wire longitudinally within the lumen.

15. A probe as in Claim 12 wherein the distal extremity of the flexible elongate member includes first and second sections, the second section being more flexible than the first section for facilitating bending at the second section.

16. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities and extending along a longitudinal axis, a plurality of longitudinally-extending spaced-apart arms, means interconnecting the proximal extremities of the plurality of arms to the distal extremity of the flexible elongate tubular member, means interconnecting the distal extremities of the plurality of arms, the plurality of arms being movable between a contracted position and an expanded position and being spaced closely together in a group extending along the first side of the longitudinal axis when in the expanded position, a plurality of longitudinally spaced-apart electrodes carried by each of the plurality of arms for engaging the wall of the heart when the plurality of arms are in the expanded position and electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes, the flexible elongate tubular member having at least one lumen extending between the proximal and distal extremities, at least one additional arm slidably carried within the lumen and having a distal extremity, means for securing the distal extremity of the additional arm to the interconnected distal extremities of the plurality of arms, the additional arm being bowable outwardly from a second side of the longitudinal axis generally opposite the first side for engaging the wall of the heart whereby movement of the additional arm distally in the lumen causes the distal

extremity of the additional arm to engage a portion of the wall of the heart and thus urge the electrodes carried by the plurality of arms against a second portion of the wall generally opposing the first-named portion of the wall.

17. A probe as in Claim 16 wherein at least two additional arms are slidably disposed in the flexible elongate tubular member and bow outwardly from the second side of the longitudinal axis for urging the electrodes against the second portion of the wall.

18. A probe as in Claim 16 wherein the distal extremity of the additional arm is formed with a spring-like member having a predetermined bowed shape.

19. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities, a lumen extending along a longitudinal axis between the proximal and distal extremities, a plurality of at least four longitudinally-extending spaced-apart arms, means interconnecting the proximal extremities of the arms to the distal extremity of the flexible elongate tubular member, means interconnecting the distal extremities of the arms, the arms movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis, the arms subtending an angle of approximately 120° or less about the longitudinal axis when in the expanded position, a plurality of longitudinally spaced-apart electrodes carried by each of the arms, electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes, a wire slidably carried within the lumen having proximal and distal end portions, the means interconnecting the distal extremities of the arms securing the distal end portion of the wire to the distal extremities of the arms, means carried by the proximal extremity of the flexible elongate tubular member for pulling the proximal end portion of the wire to cause the arms to move to the expanded position, the flexible elongate tubular member having a proximal section and a highly flexible section which is more flexible than the proximal section, means carried by the flexible elongate tubular member for bending the distal extremity of the flexible elongate tubular member at the highly flexible section to move the electrodes carried by the arms toward a portion of the wall whereby the electrodes carried by the arms can be urged against said portion of the wall of the heart when the arms are in the expanded position to map said portion of the wall.

20. A probe as in Claim 19 wherein a plurality of at least eight electrodes are carried by each of the arms.

21. In an apparatus for mapping the wall of a chamber of a heart having blood therein, a flexible elongate tubular member having proximal and distal extremities and at least one lumen extending between the proximal and distal extremities, expandable means carried by the distal extremity of the flexible elongate tubular member and being movable between contracted and expanded positions, a plurality of spaced-apart electrodes carried by the expandable means for engaging the wall of the heart and arranged in a pattern, the expandable means having spaces between electrodes when the expandable means is in the expanded position and a plurality of radiopaque markers carried by the expandable means and arranged in the pattern whereby the plurality of radiopaque markers arranged in the pattern facilitate location of the plurality of electrodes within the heart.

22. The apparatus of Claim 21 wherein the expandable means includes a plurality of longitudinally extending arms having interconnected distal extremities, the plurality of electrodes carried by the arms in longitudinally spaced-apart positions.

23. The apparatus of Claim 22 wherein the arms are circumferentially spaced-apart to form a basket-like assembly.

24. The apparatus of Claim 21 wherein the electrodes each have an outer surface formed from platinum black for reducing the impedance of the electrodes.

25. A method for mapping an apex of chamber of a heart formed by a wall with a catheter probe having a flexible elongate tubular member extending along a longitudinal axis and having proximal and distal extremities, a plurality of longitudinally-extending spaced-apart arms having proximal extremities and interconnected distal extremities carried by the distal extremity of the flexible elongate tubular member and movable between a contracted position and an expanded position in which the arms bow outwardly from the longitudinal axis, a plurality of longitudinally spaced-apart electrodes mounted on each of the arms, comprising the steps of introducing the arms into the chamber, extending the arms across the apex of the chamber and moving the interconnected distal extremities of the arms distally to facilitate engagement of the electrodes mounted on the arms with the apex of the chamber whereby the electrodes sense electrical signals from wall to permit mapping about the apex.

26. A method as in Claim 25 wherein the catheter probe includes a wire slidably carried by the flexible elongate tubular member, the wire having a distal end portion joined to the interconnected distal extremities of the arms, wherein the moving step includes pushing the interconnected distal extremities of the arms with the wire.

27. A method as in Claim 25 wherein the arms subtend an angle of approximately 180° or less about the longitudinal axis when in the expanded position.

28. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities, expandable means capable of moving from a contracted position to an expanded position secured to the distal extremity of the flexible elongate tubular member and formed from at least two elongate members movable between contracted and expanded positions, the elongate members having extremities which are joined so that the elongate members extend at an angle relative to each other to form a vee therebetween, a plurality of longitudinally and radially spaced-apart electrodes carried by the expandable means so that they can be moved into engagement with the wall of the heart when the expandable means is expanded into the expanded position, electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes and an elastomeric material adhered to the joined extremities of the elongate members and disposed within the vee for inhibiting the formation of thrombus on the elongate members while the expandable means is disposed within the blood of the heart.

29. A probe as in Claim 28 wherein the elastomeric material forms a web in the vee.

30. A probe as in Claim 29 wherein the elastomeric material consists of polyurethane.

31. A probe as in Claim 28 wherein the elongate members consist of arms and wherein the extremities consist of the distal extremities of the arms.

32. A probe as in Claim 31 wherein the arms extend at an acute angle relative to each other.

33. A probe as in Claim 28 wherein the expandable means consists of a basket assembly having a plurality of longitudinally-extending radially spaced-apart elongate arms having joined proximal and distal extremities, the joined distal extremities of an adjacent pair of arms forming the vee.

34. A probe as in Claim 33 wherein the elongate arms include a group of arms which are spaced relatively closely together and at least one support arm aligned generally opposite the group of arms, the plurality of electrodes being carried in longitudinally spaced-apart positions on the group of arms and the at least one support arm serving to urge the group of arms against the wall of heart so as to permit high density mapping of the wall of the heart from electrical signals sensed from the wall by the electrodes.

35. A probe as in Claim 28 together with an antithrombogenic agent carried by the expandable means for inhibiting the formation of thrombus on the expandable means while the expandable means is disposed within the blood of the heart.

36. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities and at least one lumen extending therethrough, a basket assembly movable between contracted and expanded positions, the basket assembly having a plurality of longitudinally-extending circumferentially spaced-apart arms with proximal and distal extremities, means for joining the proximal extremities of the arms to the distal extremity of the flexible elongate tubular member, means for joining together the distal extremities of the arms, a plurality of longitudinally spaced-apart electrodes carried by each arm for engaging the wall of the heart when the basket assembly is expanded into the expanded position, electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes and an elastomeric material disposed between the joined distal extremities of the arms for eliminating acute angles and inhibiting the formation of thrombus on the basket assembly while the basket assembly is disposed within the blood of the heart.

37. A catheter probe as in Claim 36 further comprising additional elastomeric material disposed between the proximal extremities of adjacent arms for eliminating acute angles therebetween.

38. A probe as in Claim 37 together with an antithrombogenic agent carried by the basket assembly.

39. A probe as in Claim 36 wherein the elastomeric material includes a web extending between the joined distal extremities of each adjacent pair of arms.

40. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities and extending along a longitudinal axis, a basket assembly carried by the distal extremity of the flexible elongate tubular member and having first and second generally opposite sides relative to the longitudinal axis, the basket assembly movable between contracted and expanded positions and having a plurality of longitudinally-extending spaced-apart arms with proximal and distal extremities, the plurality of arms being spaced closely together in a group extending along the first side of the basket assembly, the basket assembly having at least one additional arm extending along the second side of the basket assembly, means for joining together the distal extremities of the arms, a plurality of longitudinally spaced-apart electrodes carried by each of the plurality of arms for engaging the wall of the heart when the basket assembly is expanded into the expanded position and electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes whereby the at least one additional arm urges the electrodes carried by the plurality of arms against the wall of the heart when the basket assembly is expanded into the expanded position.

41. A probe as in Claim 40 wherein the plurality of arms range between three and six in number.

42. A probe as in Claim 40 wherein the plurality of arms subtend an angle of less than 180° about the longitudinal axis.

43. A probe as in Claim 42 wherein the plurality of arms subtend an angle of approximately 90° about the longitudinal axis.

44. A probe as in Claim 40 wherein the basket assembly has a longitudinal dimension which approximates the longitudinal dimension of the chamber of the heart.

45. A probe as in Claim 40 wherein the electrodes create a pattern of closely-spaced electrodes for permitting high density mapping of a region of the wall.

46. A probe as in Claim 45 wherein the basket assembly has a longitudinal dimension significantly less than the longitudinal dimension of the chamber of the heart so as to permit the closely-spaced electrodes to be moved longitudinally within the chamber to another region of the wall.

47. A probe as in Claim 40 together with an elastomeric material disposed between the joined distal extremities of the plurality of arms for inhibiting the formation of thrombus on the basket assembly while the basket assembly is disposed within the blood of the heart.

48. A probe as in Claim 40 wherein the electrodes on adjacent arms are longitudinally offset relative to each other.

49. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities and extending along a longitudinal axis, a plurality of longitudinally-extending spaced-apart arms with interconnected proximal extremities and interconnected distal extremities carried by the distal extremity of the flexible elongate tubular member, the arms movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis, the arms subtending an angle of approximately 180° or less about the longitudinal axis when in the expanded position, a plurality of longitudinally spaced-apart electrodes carried by each of the arms for engaging the wall of the heart when the arms are moved into the expanded position and electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes whereby the electrodes carried by the arms can be urged against a portion of the wall of the heart when the arms are in the expanded position for performing high density mapping of said portion of the wall.

50. A probe as in Claim 49 wherein the arms subtend an angle of approximately 90° or less about the longitudinal axis when in the expanded position.

51. A probe as in Claim 50 wherein the arms range between three and six in number.

52. A probe as in Claim 49 together with an elongate member having a proximal extremity carried by the distal extremity of the flexible elongate tubular member and a distal extremity, means for securing the distal extremity of the elongate member to the distal extremities of the arms.

53. A probe as in Claim 52 wherein the elongate member consists of an additional arm which is disposed generally opposite the arms and is movable between a contracted position and an expanded position in which the additional arm bows outwardly from the longitudinal axis.

54. A probe as in Claim 49 wherein the arms each include a spring-like member extending therealong which has a predetermined shape corresponding substantially to the expanded position of the arm.

55. In a catheter probe for introduction into a chamber of the heart having blood therein and formed by a wall through a lumen leading to the chamber, a flexible elongate tubular member having proximal and distal extremities and extending along a longitudinal axis, a plurality of longitudinally-extending spaced-apart arms carried by the distal extremity of the flexible elongate tubular member, the arms movable between a contracted position and an expanded position in which they bow outwardly from the longitudinal axis, each of the arms including a spring-like strip extending therealong which has a predetermined shape corresponding generally to the expanded position of the arm, the arms subtending an angle of approximately 180° or less about the longitudinal axis when in the expanded position, a plurality of longitudinally spaced-apart electrodes carried by each of the arms for engaging the wall of the heart when the arms are moved into the expanded position and electrical means extending through the elongate tubular member and connected to the electrodes for performing electrical functions with respect to the electrodes whereby the electrodes carried by the arms can be urged against a portion of the wall of the heart when the arms are in the expanded position for performing high density mapping of said portion of the wall.

56. A probe as in Claim 55 wherein the strip is made from a shape memory alloy.

57. In an apparatus for mapping a wall of a chamber of the heart, a flexible elongate member having proximal and distal extremities, expandable means carried by the distal extremity of the flexible elongate member for moving between contracted and expanded positions, the expandable means having a plurality of elongate flexible spaced-apart arms with distal extremities and means for joining together the distal extremities of the arms, a plurality of spaced-apart electrodes carried by the expandable means for engaging the wall of the heart when the expandable means is moved to its expanded position, the means for joining together the distal extremities of the arms including a rounded distal tip formed from a soft material for inhibiting the formation of trauma in the wall of the heart upon engagement of the tip with said wall.

58. An apparatus as in Claim 57 wherein the soft material is an elastomeric material.

59. An apparatus as in Claim 57 wherein the soft material is silicone.

60. An apparatus as in Claim 57 wherein the expandable means is a basket assembly having a plurality of spaced-apart arms, a plurality of longitudinally spaced-apart electrodes carried by each of the arms for mapping the wall of the heart.

61. An apparatus as in Claim 60 wherein the plurality of arms are circumferentially spaced apart.

62. An apparatus as in Claim 60 wherein the plurality of arms are relatively closed spaced apart for permitting high density mapping of a portion of the wall of the heart.

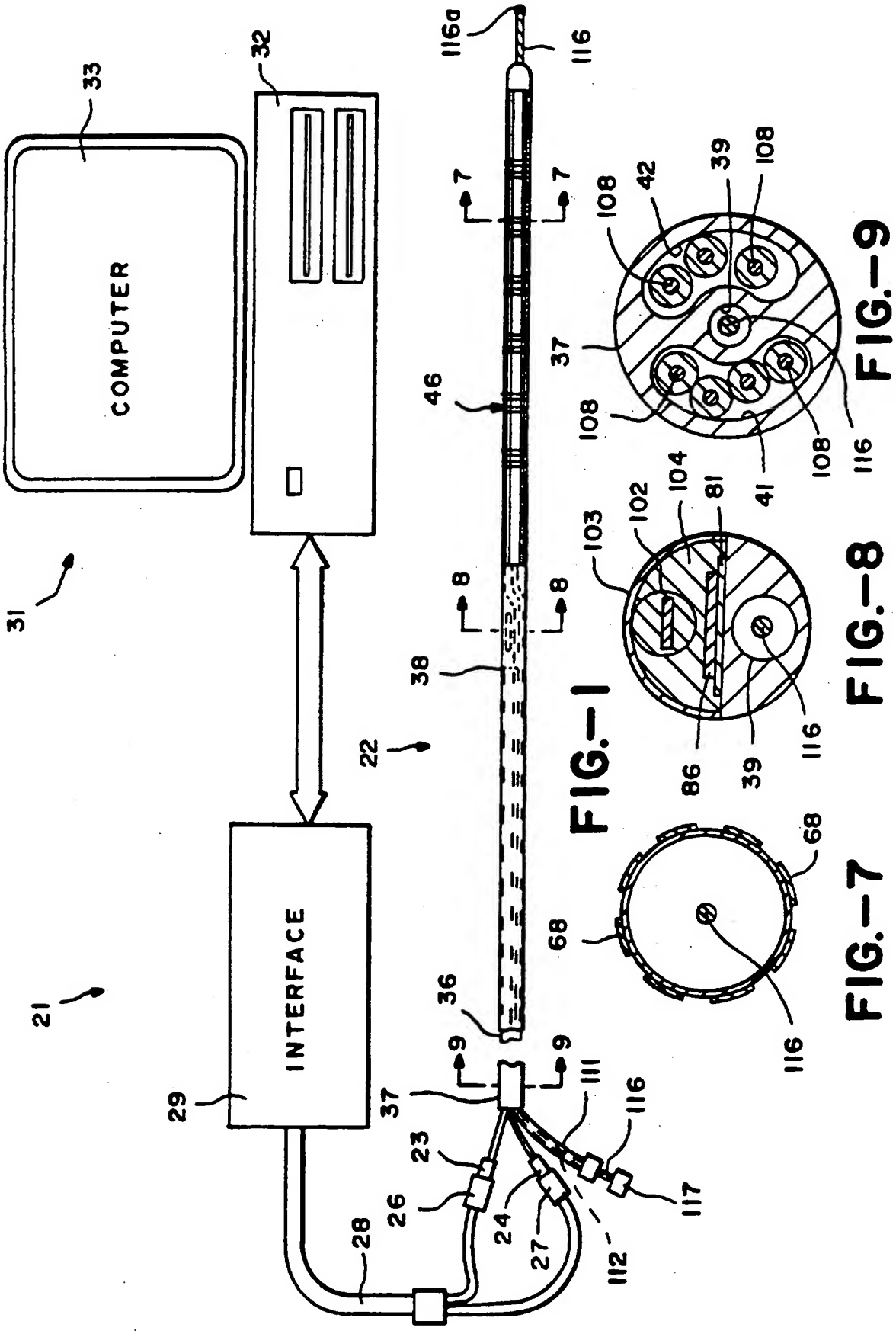

FIG.—1

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FIG.—8

FIG.—9

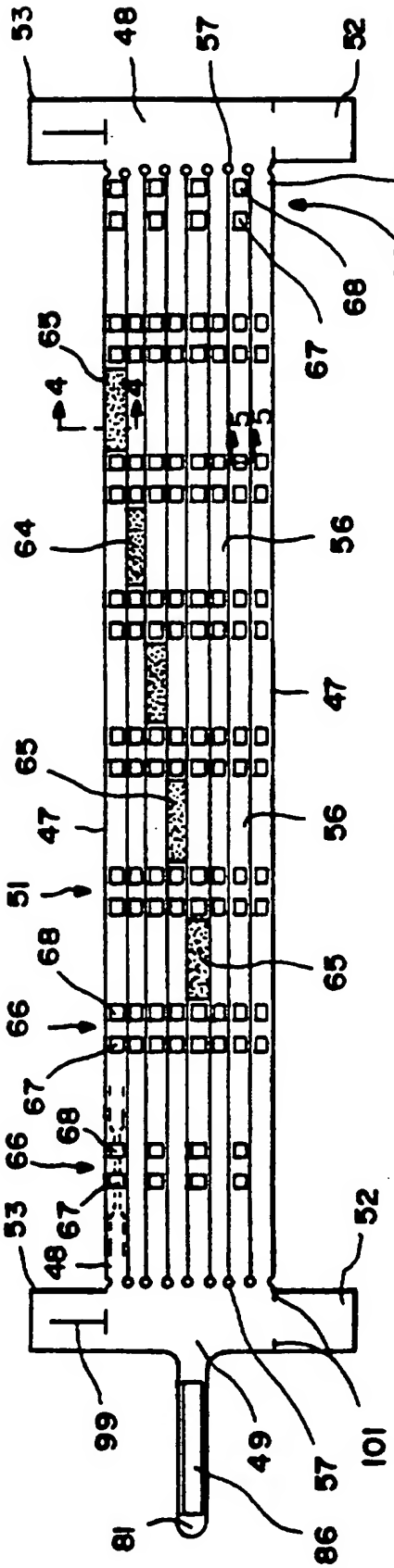


FIG.-2

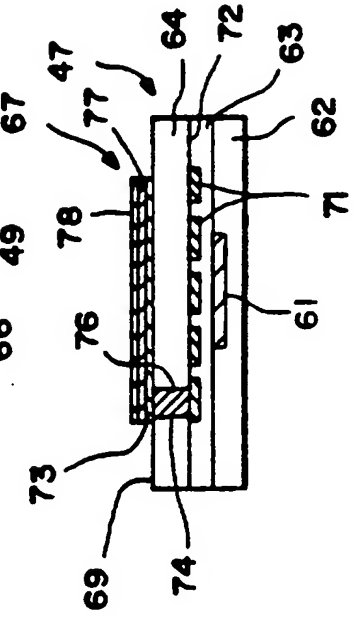


FIG.-5

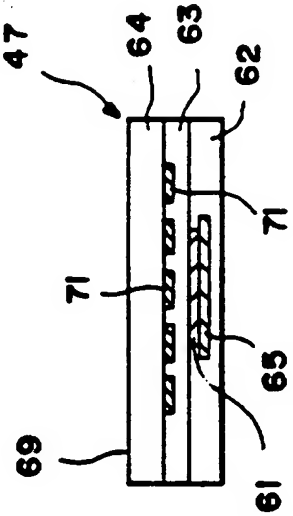


FIG.-4

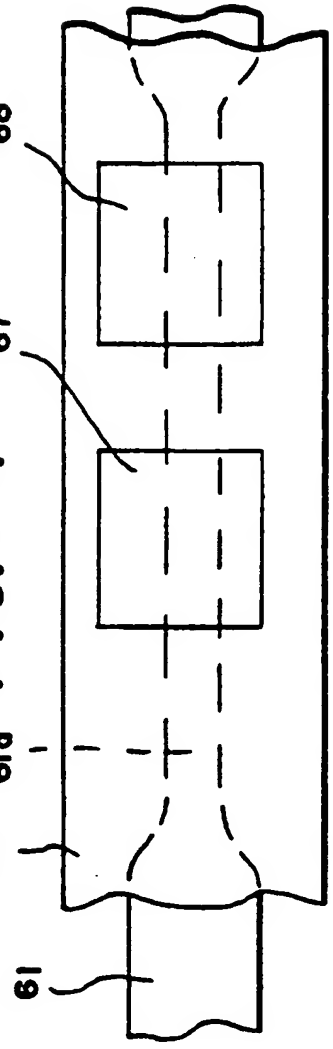


FIG.-3

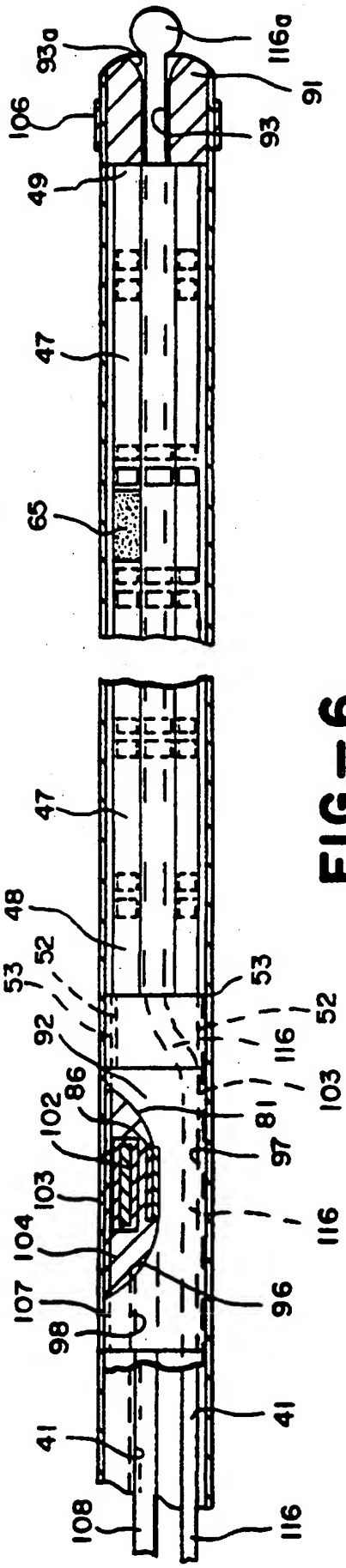


FIG.—6

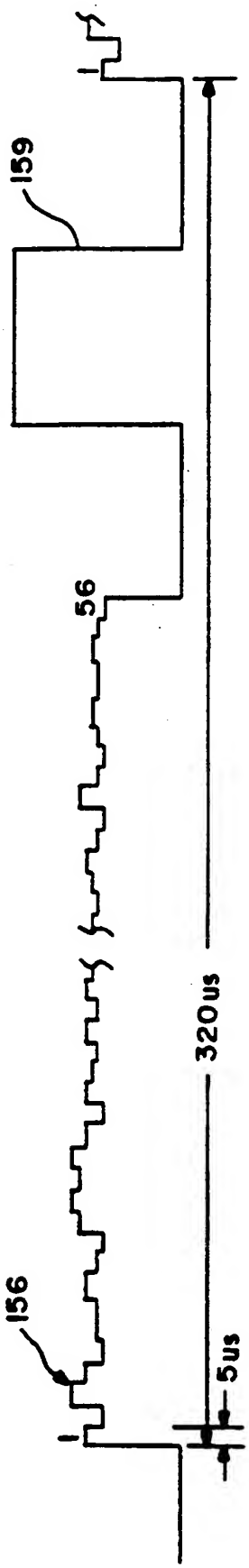


FIG.—13

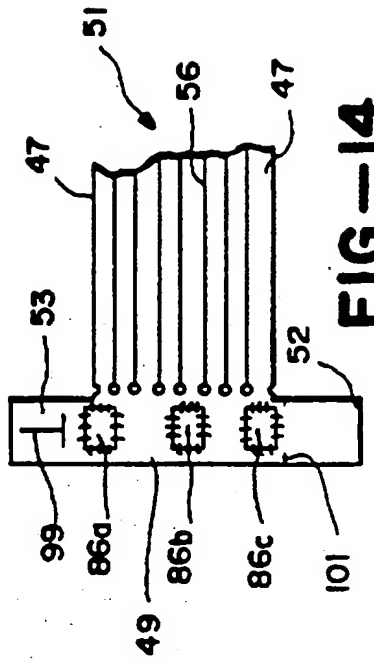


FIG.—14

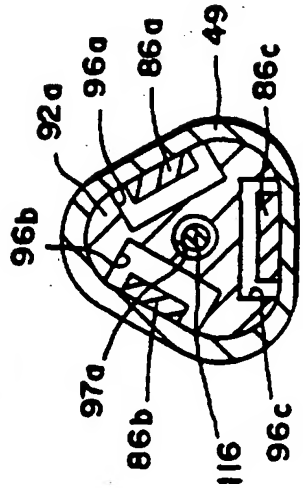
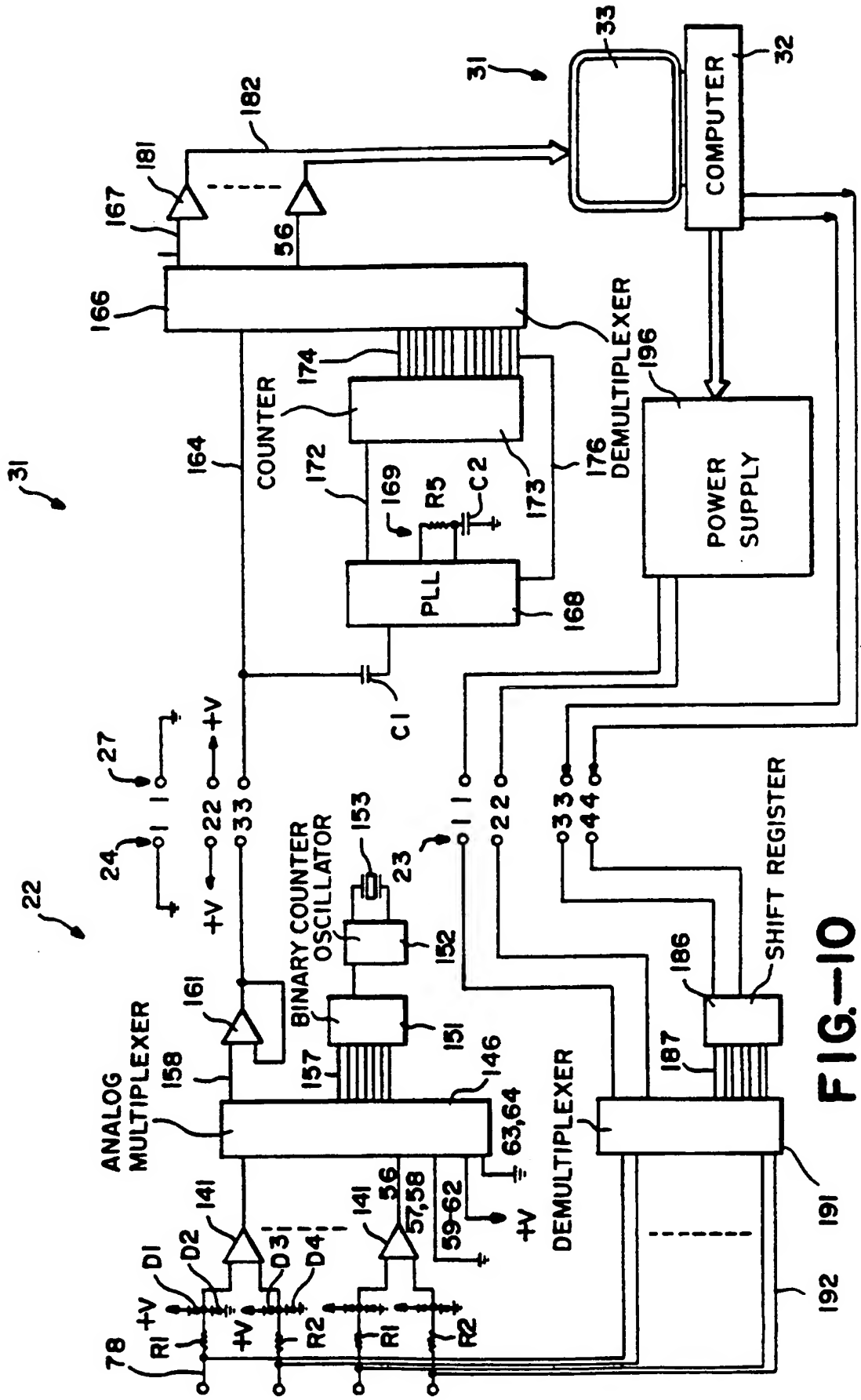


FIG.—15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POWER SUPPLY
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R5
C2
173
176
PLL
168
C1
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+V
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BINARY COUNTER OSCILLATOR
152
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158
ANALOG MULTIPLEXER
63,64
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D1
D2
D3
D4
R1
R2
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SHIFT REGISTER
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DEMULTIPLEXER
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FIG.—10

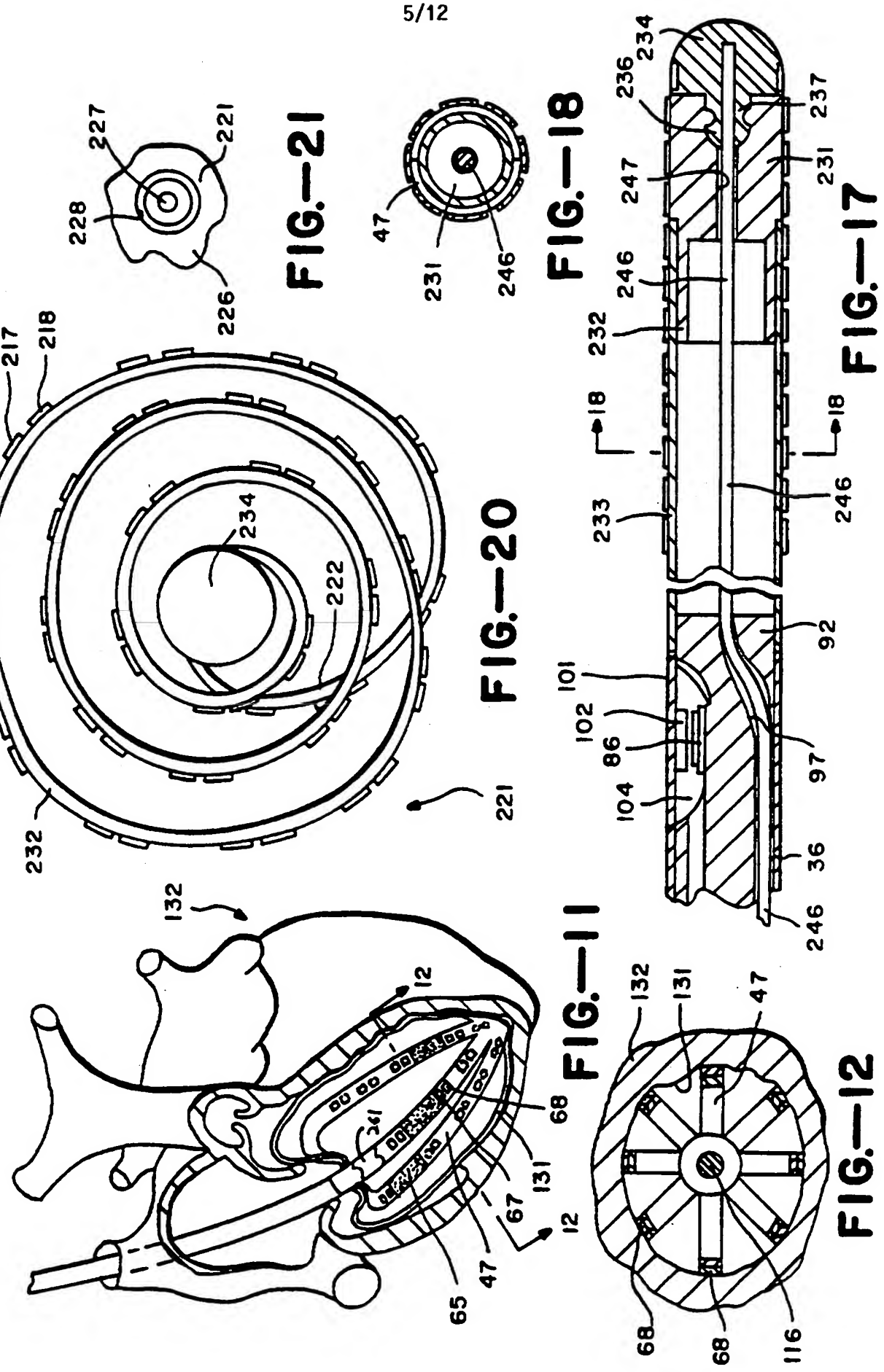
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FIG.—11
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FIG.—20

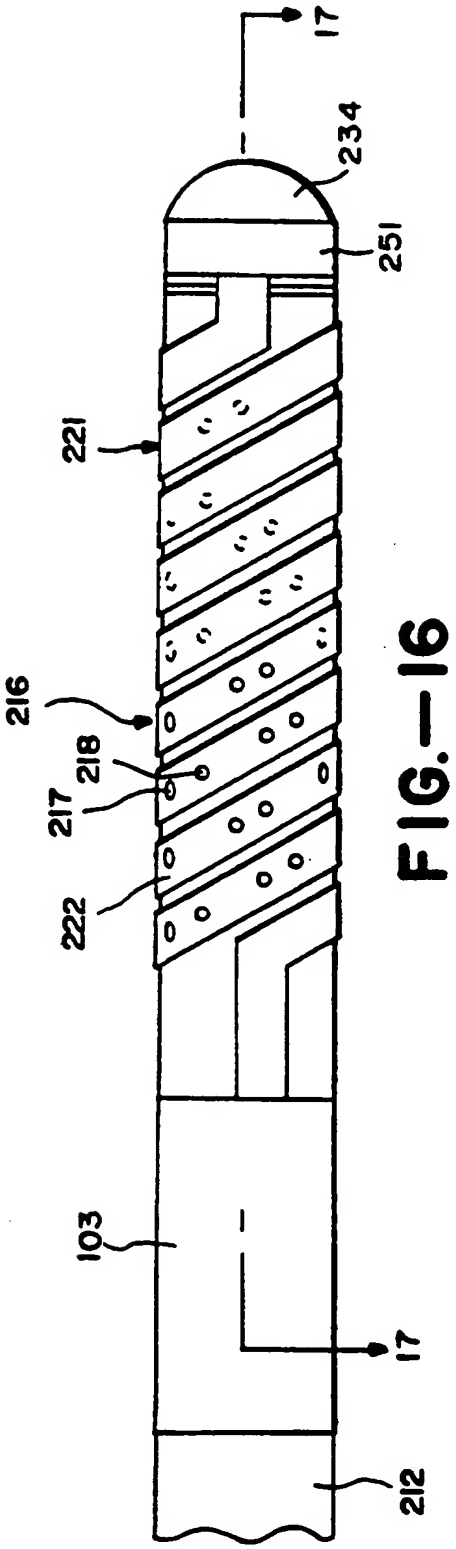
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FIG.—16

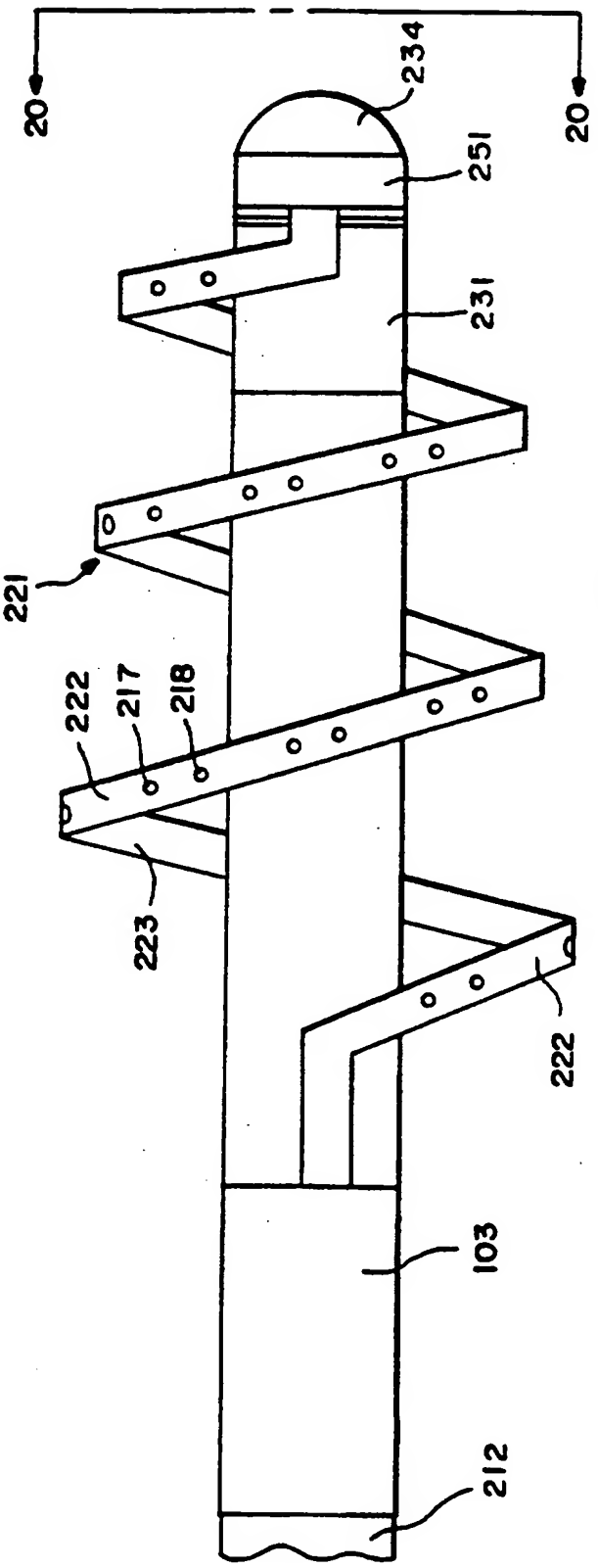
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FIG.—19

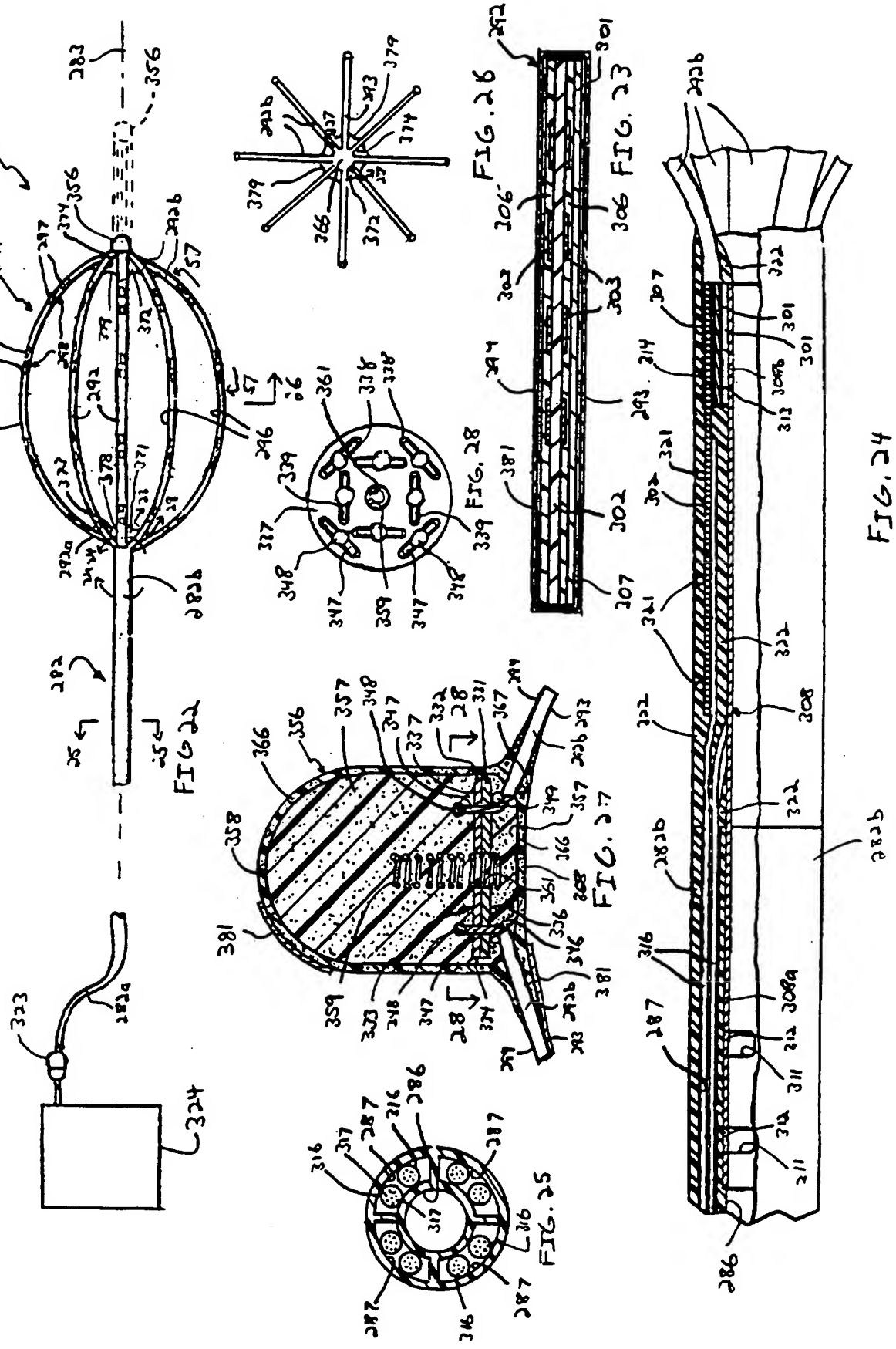
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FIG. 28

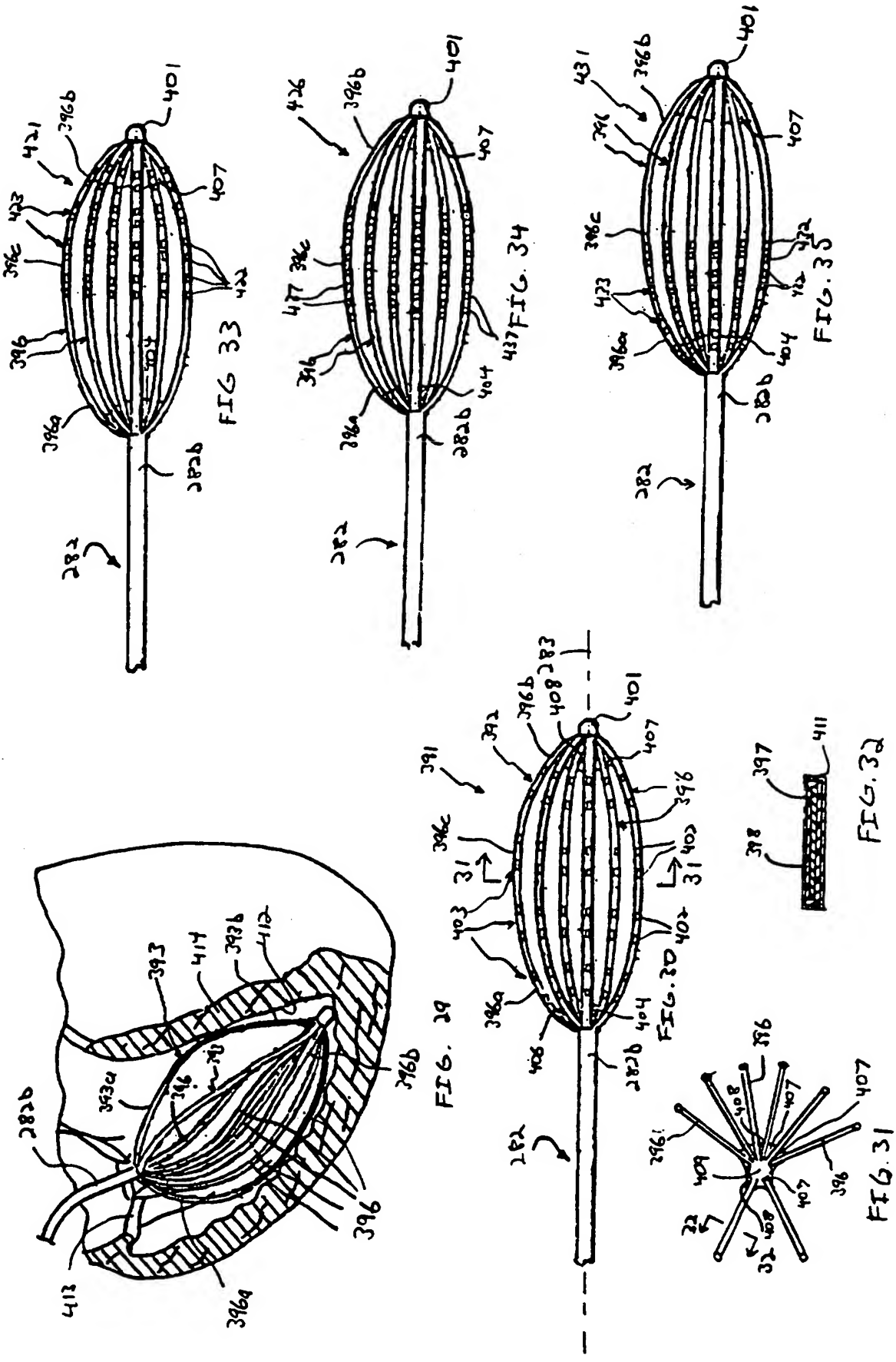
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FIG. 33
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FIG. 36

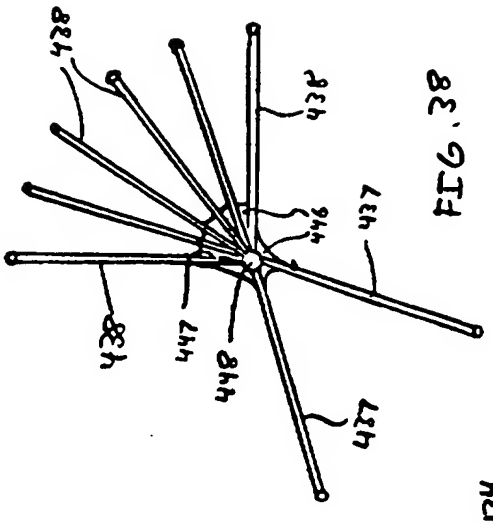

FIG. 38

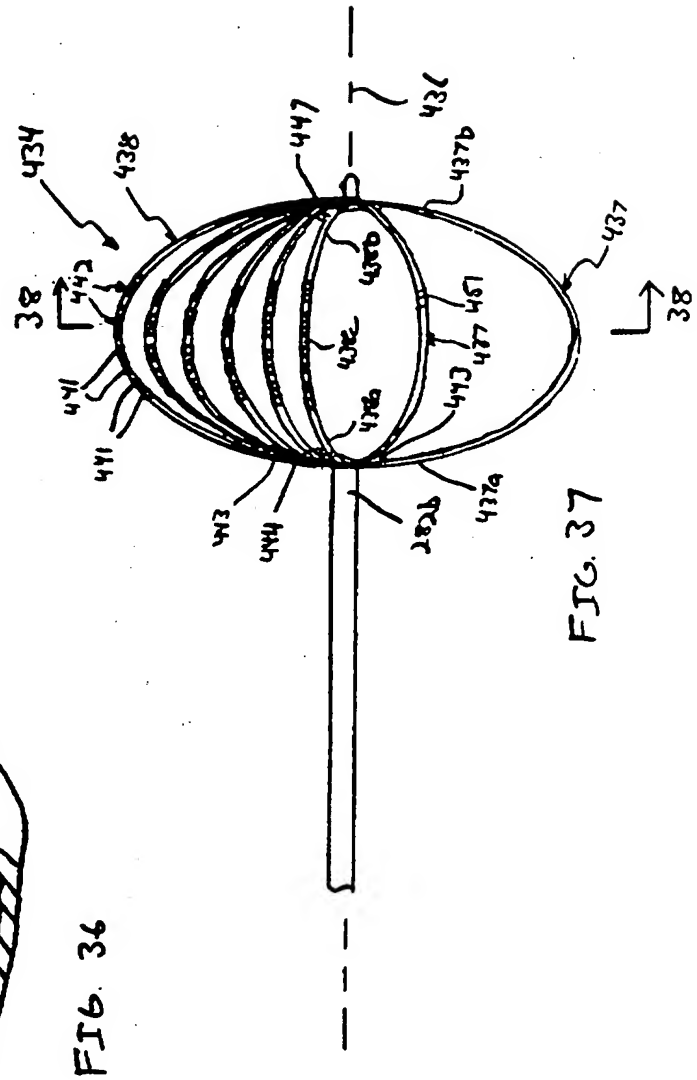

FIG. 37

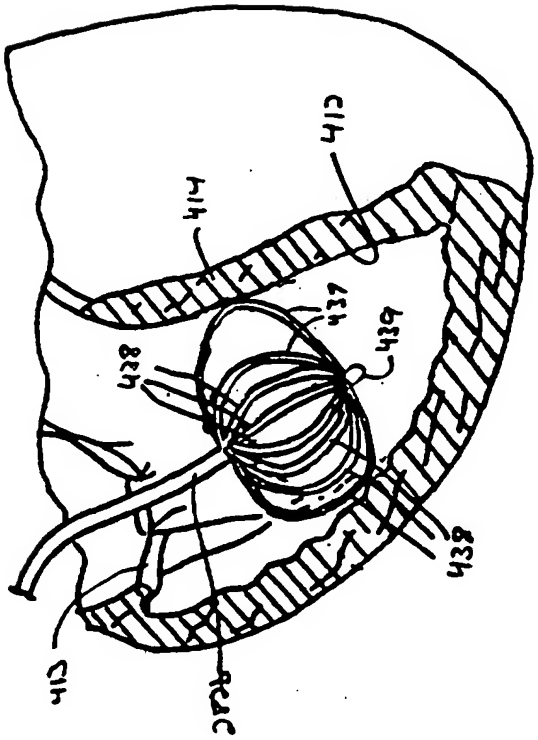

FIG. 36

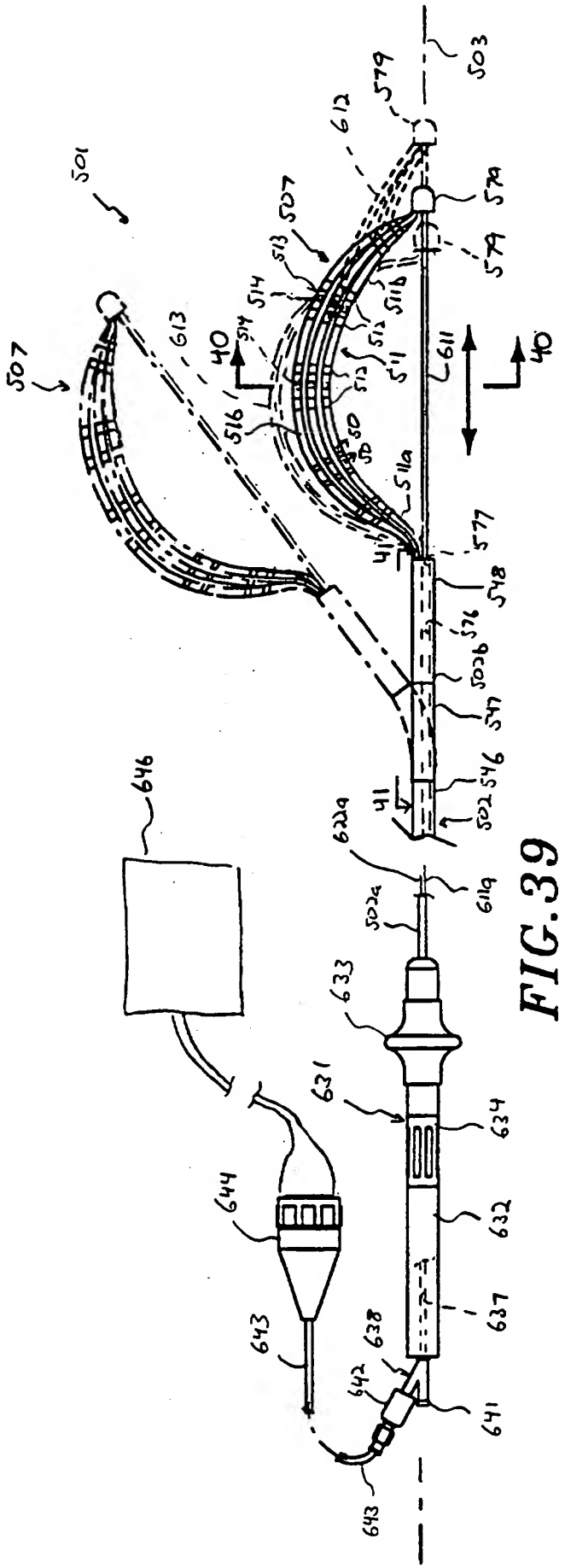

FIG. 39

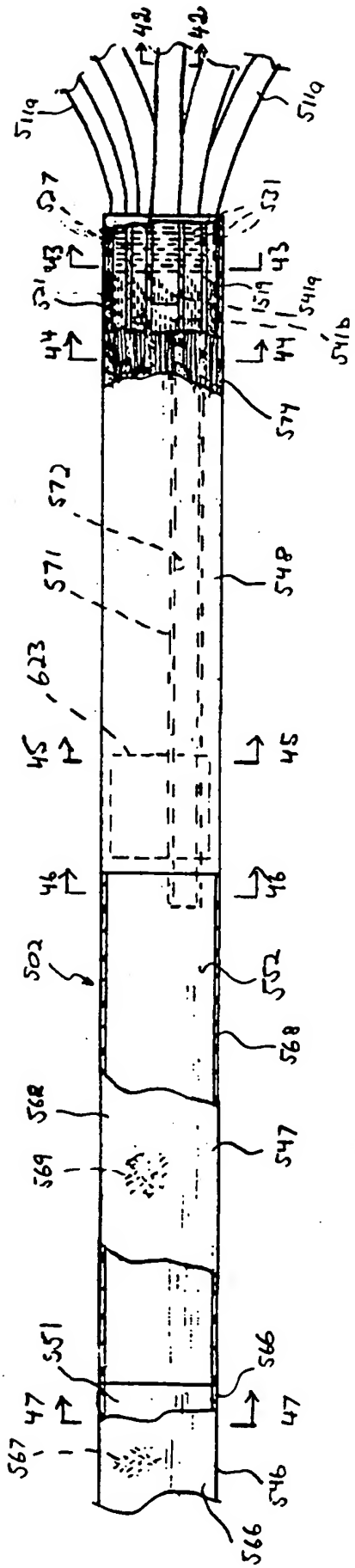

FIG. 41

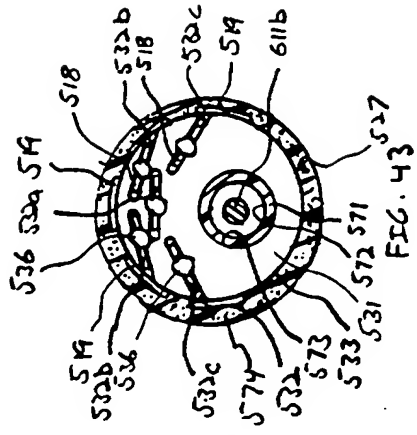

FIG. 43

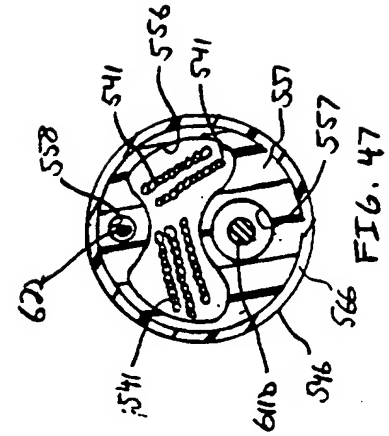

FIG. 47

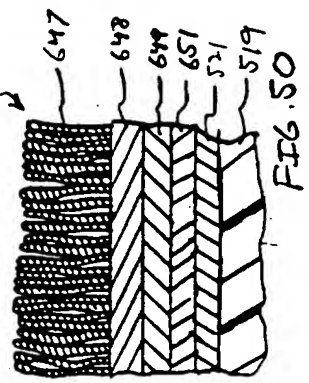

FIG. 50

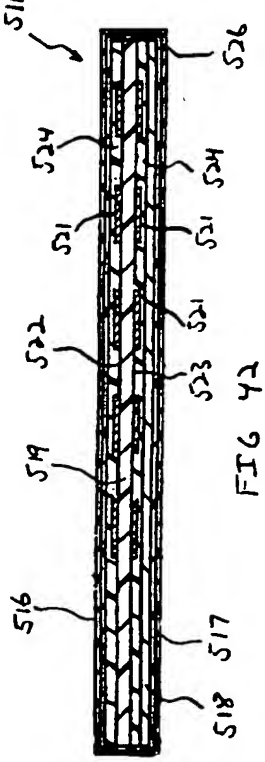

FIG 42

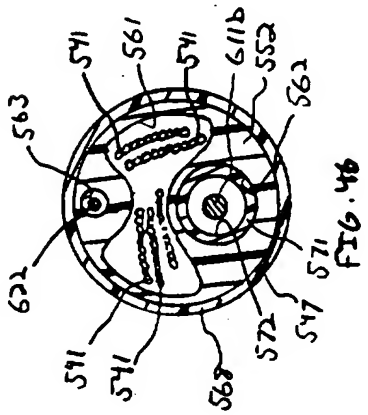

FIG. 46

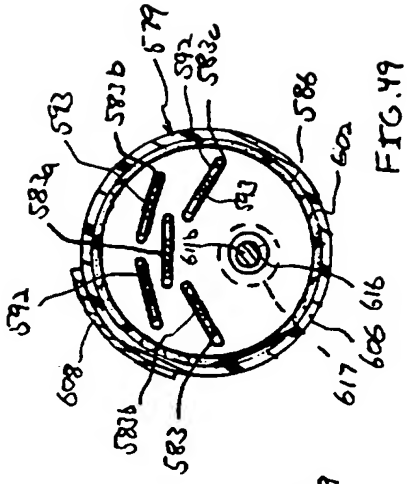

FIG. 49

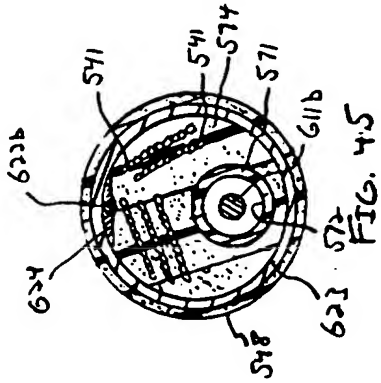

FIG. 45

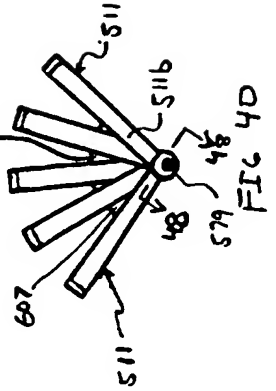

FIG 4D

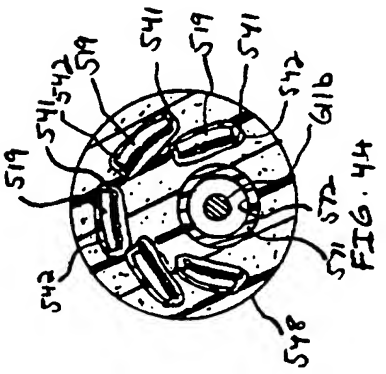

FIG. 44

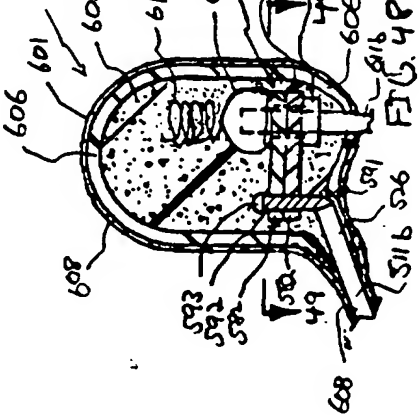

FIG. 48

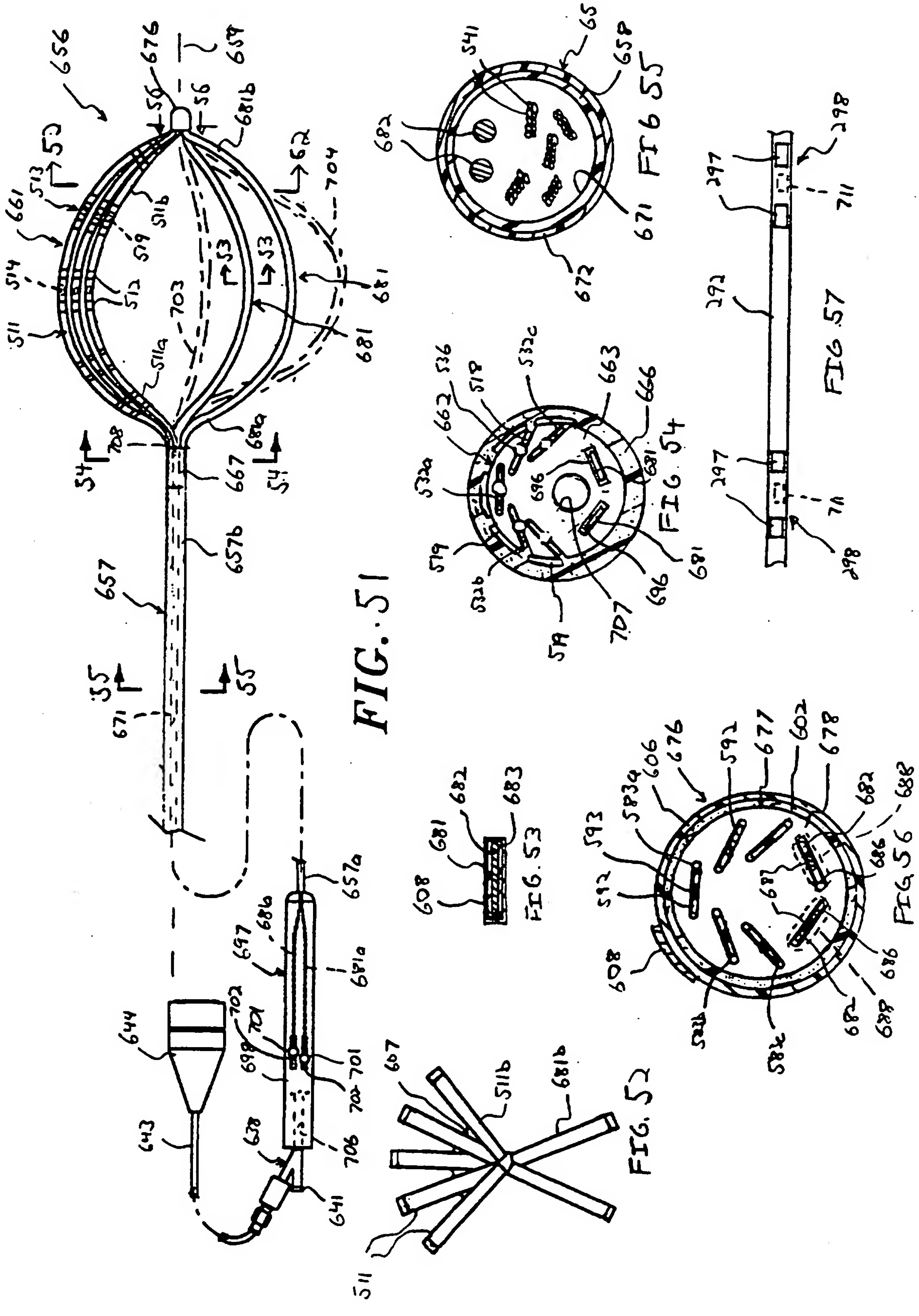
FIG. 51
FIG. 52
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FIG. 55
FIG. 56
FIG. 57

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/18204

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/04
US CL :128/642

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642; 606/041; 607/122, 125, 126

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X/Y, P	US 5,558,073 A (Pomeranz et al.) 24 SEPTEMBER 1996 see entire document.	1-8, 10-134, 36, 37, 39-56/ 35, 38
X/Y	US 5,255,679 A (Imran) 26 OCTOBER 1993, see entire document.	1-8, 10-20,. 25-28, 31-34, 36, 40-56/ 35, 38
X/Y, P	US 5,499,981 A (Kordis) 19 MARCH 1996, see entire document.	1-20, 25-29, 31-34, 36, 37, 39-62/ 35, 38
Y	US 5,053,048 A (Pinchuk) 01 OCTOBER 1991, see entire document.	35, 38

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 20 DECEMBER 1996	Date of mailing of the international search report 03 FEB 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JEFFREY R. JASTRZAB Telephone No. (703) 308-0858

Form PCT ISA/210 (second sheet)(July 1992)*